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MAJOR TRAUMA IN SCOTLAND

DEVELOPMENT AND PROGRESS OVER A DECADE

Colin Alexander Graham

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MAJOR TRAUMA IN SCOTLAND

DEVELOPMENT AND PROGRESS OVER A DECADE

Major trauma in Scotland

Development and progress over a decade

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Thesis submitted in fulfilment of
the requirements for the degree of

Doctor of Medicine

Division of Community Based Sciences

Faculty of Medicine

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Abstract

Background

Major trauma (defined as injury severity score >15) remains a major public health issue. Trauma mortality in Scotland has decreased over time, but functional outcome following trauma is poorly understood. Better knowledge of post-trauma morbidity could potentially influence acute management and rehabilitation. Individual aspects of the trauma care process, from prehospital care, through emergency department (ED) resuscitation, to definitive care, all play crucial roles in optimising outcome from major trauma.

Objective

Using seven studies and various methodologies, this thesis describes progress in trauma management in Scotland over the last decade, including epidemiology, prehospital care, emergency department care and functional outcome.

Design

A prospective case-control study examined functional outcome following major trauma. The remaining studies consisted of one Scotland-wide prospective multicentre observational study; two retrospective studies utilising the Scottish Trauma Audit Group (STAG) database; one retrospective cohort study combining data from STAG and the national multicentre study; one prospective clinical cohort study; and one prospective observational study with STAG examining prehospital care across the West of Scotland.

Settings

City of Glasgow; seven university teaching hospital EDs across Scotland; the STAG database (gathering data from 1992-2002 on >50 000 injured patients); a Scottish district general hospital ED; that part of the West of Scotland served by the Institute of Neurological Sciences at the Southern General Hospital.

Participants

For the study of functional outcome, 223 patients who were resuscitated in one of four Glasgow hospital EDs at least two years prior to study entry were eligible; 19 patients participated with 7 controls. For the Scottish prospective multicentre observational study, 439 intubated trauma patients. For the three studies involving STAG, the database consisted of 34 903 patients, and final numbers of participants were 5 154, 1 469 and 27. For the observational study of the West of Scotland, the study population totalled 2.58 million and final participants were 3 962 urban and 674 rural patients. The cohort study was done in an ED which sees 54 000 patients annually; 1 378 children participated.

Outcome measures

For outcome assessment: American Medical Association (AMA) Impairment Score; Functional Independence Measure (FIM); Community Integration Questionnaire (CIQ); Short-Form 36 (SF36) questionnaire; and work status. For the other studies: mortality; number of inpatient and intensive care days; laryngoscopic views obtained; complications of intubation; and various specific observational outcomes.

Results

Non-head injured survivors of major trauma treated in Glasgow hospitals more than two years previously are more impaired than suitable controls; have lower SF36 mental component summary scores than controls and the general UK population; have lower physical component summary scores than the UK and US populations; have little difference in employment status compared to controls; and came from similarly deprived areas compared to controls.

SF36 mental and physical summary scores are both decreased below the UK means suggesting that clinical improvement could occur in those areas.

However, the high return to work rate and high FIM scores suggest that lack of physical ability is not a major issue in terms of functional outcomes.

Cervical spine injury was shown to have no relationship with the ED GCS, although patients who were GCS 3 were more likely to have cervical spine injuries. The incidence of cervical spine injury after blunt head injury was found to be 5.3%. Spinal cord injury due to penetrating trauma is rare in Scotland. Longer prehospital times in rural Scotland do not increase mortality compared to shorter prehospital times in the urban environment.

Trauma intubation is equally effective whether performed by anaesthetists or emergency physicians in the ED. A small proportion of critically injured patients who are intubated in the ED without drugs may survive. With respect to children's trauma, focusing on school incidents, better use of cycle helmets and increasing adult supervision particularly in the 5-13 year age group may decrease the incidence of trauma.

Conclusions

Firstly, outcome following trauma in Scotland is poorly understood, partially due to ethical and practical difficulties of accessing patients and information. The practical problems remain challenging, but consent, access and data protection issues may be minimised by utilising a registry based design for major trauma follow up throughout Scotland.

Secondly, this work can suggest the tools that should be used for future research. Such tools must be user and patient friendly, and it should be possible for any trained health care professional to use them. The SF36 is suitable, well tested and useful. The AMAIS is not suitable given its complexity, and the FIM has significant ceiling effects which minimise its usefulness. The CIQ is promising but requires larger scale study to identify its precise role.

Impairment itself, along with ability, may be relatively unimportant in a global health assessment strategy, whereas participation and work status along with overall health status may be much more important and relevant to the individual, to health care systems and to society.

Thirdly, the data in this work suggests that despite survivors having more impairment than controls and poorer health status, they have little difference in employment status. Further clarification of the complex relationship between health status and impairment may potentially increase the proportion of patients who return to work after trauma.

The importance of spinal immobilisation for blunt trauma patients was demonstrated by the incidence of 5.3% for cervical spine injury after blunt head injury. In contrast, fully conscious patients who sustain isolated penetrating trauma do not require cervical spine immobilisation. Rationalisation of trauma services in Scotland and concentration of trauma workload in fewer centres may not lead to poorer trauma outcomes.

Trauma intubation was shown in a national multicentre study to be equally efficacious in the hands of emergency physicians and anaesthetists in Scotland. Contrary to previous work, critically injured patients who are intubated in the ED without drugs may survive with aggressive resuscitation.

For children, targeting school incidents, increasing use of cycle helmets and improving adult supervision particularly in the 5-13 year age group may have some impact on the incidence of trauma.

Finally, future directions in the approach to trauma care in Scotland are explored and discussed.

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Table of Contents

Abstract	3
Acknowledgements	8
Table of Contents	11
List of Figures	18
List of Tables	20
Glossary	21
Personal statement and structure of MD thesis	23
Approach to the scientific literature	30
 Section A: Long term outcome of major trauma in Scotland	 31
 1: Introduction	 32
 2: Background	 37
2.1: Significance of major trauma in Scotland	37
2.2: Definition of major trauma	38
2.3: Morbidity of major trauma in the UK	39
 3: Literature review	 40
3.1: Search strategy	40
3.2: Major trauma	42
3.2.1: UK studies	42
3.2.2: North American studies	52
3.2.3: European studies	58
3.2.4: Specific types of trauma	65
3.2.4.1: Outcome after intensive care	65

3.2.4.2: Outcome after lower limb injury	69
3.2.4.3: Outcome after upper limb injury	74
3.2.4.4: Outcome after paediatric major trauma	75
3.2.4.5: Outcome after major trauma in the elderly	78
3.2.4.6: Outcome after major trauma in women	81
3.2.4.7: The impact of minor head injury	84
3.2.5: Summary of trauma literature	86
3.3: Outcome indicators	87
3.3.1: Assessment of impairment	87
3.3.1.1: American impairment scale	87
3.3.1.2: Other scales	88
3.3.2: Assessment of activity (disability/functional outcome)	89
3.3.2.1: Functional independence measure	89
3.3.2.2: Barthel index	91
3.3.2.3: Functional capacity index	92
3.3.2.4: Other measures	93
3.3.3: Assessment of participation (handicap)	95
3.3.3.1: Community integration questionnaire	95
3.3.3.2: Other measures	96
3.3.4: Assessment of health status	96
3.3.4.1: SF36	96
3.3.4.2: SF12	98
3.3.4.3: Sickness impact profile	99
3.3.4.4: Nottingham health profile	101
3.3.5: Summary of outcome indicators	102

3.4: Summary of literature review	104
4: Aims and objectives	105
5: Research questions	106
6: Methods	108
6.1: Study design and population	108
6.2: Funding	111
6.3: Sample size calculation	111
6.4: Ethical approval	113
6.4.1: MREC	113
6.4.2: LREC	115
6.5: Consent	115
6.6: Data collection	117
6.6.1: Injury severity data	117
6.6.2: AMA impairment scale data	118
6.6.3: FIM data	119
6.6.4: CIQ data	119
6.6.5: SF36 data	120
6.6.6: Work status data	120
6.7: Questionnaire analysis	121
6.7.1: CIQ questionnaire	121
6.7.2: SF36 questionnaire	121
6.7.3: Work status questionnaire	122
6.8: Statistical analyses	123
6.9: Data protection issues	123

7: Results	124
7.1: General results	124
7.1.1: Responses from General Practitioners	124
7.1.2: Responses from trauma patients	125
7.1.3: Responses from control patients	125
7.2: Injury severity data for study population	125
7.3: Injury severity data for trauma cases	129
7.4: AMA impairment scale results	136
7.5: FIM results	138
7.6: CIQ results	140
7.7: SF36 results	142
7.7.1: MCS	142
7.7.2: PCS	144
7.7.3: MCS & PCS compared to population normal scores	146
7.8: Work status and deprivation	147
7.8.1: Employment and benefits status	147
7.8.2: Deprivation status	147
7.8.3: Impairment score, PCS and work status	149
7.8.4: Impairment score, PCS and state benefits	152
7.9: Summary of results	155
8: Discussion	156
8.1: Ethical issues	156
8.2: Characteristics of study and control group	161
8.3: Injury severity data	165
8.4: AMA impairment data	166

8.5: FIM data	167
8.6: CIQ data	168
8.7: SF36 data	169
8.8: Work status data	171
8.9: Correlations between work status, benefits & scoring systems	171
8.10: Limitations of study	172
8.11: Possible future directions	173
8.12: Summary of discussion	174
9: Conclusion	176
10: Publication resulting from this work	176
Section B: Aspects of major trauma in Scotland	177
1: Blunt cervical spine injury in Scotland	178
<p>Drainer E K, Graham C A, Munro P T. Blunt cervical spine injuries in Scotland 1995-2000. <i>Injury</i> 2003;34:330-333.</p>	
2: Penetrating spinal injury in Scotland: is spinal immobilisation required?	191
<p>Connell R A, Graham C A, Munro P T. Is spinal immobilisation necessary for all patients sustaining isolated penetrating trauma? <i>Injury</i> 2003;34:912-914.</p>	
3: Mortality following trauma intubation without drugs in Scotland	200
<p>Graham C A, Wares G M, Munro P T. Mortality after trauma intubation without drugs in Scottish emergency departments. <i>Resuscitation</i> 2006;69:395-397.</p>	

4: Children's injuries in a Scottish district general hospital	207
Graham C A, McDonald A, Stevenson J. Children's injuries in a Scottish district general hospital. <i>Injury</i> 2005; 36 :1040-1044.	
5: Rapid sequence intubation of trauma patients in Scotland	220
Graham C A, Beard D, Henry J M, McKeown D W. Rapid sequence intubation of trauma patients in Scotland. <i>Journal of Trauma</i> 2004; 56 :1123-6.	
6: Scottish urban rural trauma outcome study	236
McGuffie A C, Graham C A , Beard D, Kerr G W, Wilkie S C, Fitzpatrick M O, Henry J, Parke T R J. Scottish urban versus rural trauma outcome study. <i>Journal of Trauma</i> 2005; 59 :632-638.	
7: Investigator contributions to Section B	260
Section C: Conclusion and the future	262
1: Conclusion	263
2: The future	266
Section D: References and supporting material	268
1: Published trauma related papers during period of MD study	269
2: Trauma related presentations during period of MD study	275
3: References	283

4: Appendices	313
1 Business card for patients, relatives and GPs	314
2 Consultants in A&E Medicine – approval letter	315
3 Consultants in A&E Medicine – consent form	316
4 Initial letter of invitation to GP	317
5 GP initial response form	319
6 GP control nomination form	320
7 GP letter of introduction to patient	321
8 Patient letter of introduction	322
9 Patient information sheet	324
10 Consent form	325
11 GP letter of introduction to control	326
12 Control letter of introduction	327
13 Control information sheet	329
14 Home visit protocol	330
15 AMA impairment score data collection form	331
16 FIM data collection form	333
17 CIQ data collection form	334
18 SF36 (UK Version 1) questionnaire	336
19 Work status questionnaire	341
20 SF36 subscale scoring algorithms: first stage	342
21 SF36 subscale scoring algorithms: second stage	345
5: Declaration	346

List of Figures

A7.2.1	Distribution of age in whole group	126
A7.2.2	Distribution of injury severity scores for whole group	127
A7.2.3	Total number of inpatient days	128
A7.3.1	Age distribution for those who completed the study and those who did not	130
A7.3.2	ISS distribution for those who completed the study and those who did not	131
A7.3.3	RTS distribution for those who completed the study and those who did not	132
A7.3.4	Probability of survival distribution for those who completed the study and those who did not	133
A7.3.5	Distribution of total inpatient length of stay for those who completed the study and those who did not	134
A7.3.6	Distribution of length of intensive care unit stay for those who completed the study and those who did not	135
A7.4.1	AMA impairment scores for patients and controls	137
A7.5.1	FIM scores for patients and controls	139
A7.6.1	CIQ scores for patients and controls	141
A7.7.1	Mean MCS36 scores for patients and controls	143
A7.7.2	Mean PCS36 scores for patients and controls	145
A7.8.2	Bar chart of deprivation categories for patients and controls	148
A7.8.3.1	Impairment score and work status	150
A7.8.3.2	PCS and work status	151
A7.8.4.1	Impairment score and state benefits	153
A7.8.4.2	PCS and state benefits	154

B1.4.1	Incidence of CSI against Glasgow Coma Score	183
B1.4.2	Southern General Hospital emergency department admissions September 1996	188
B4.3.1	Questionnaire: Children's Injuries Form	210
B4.4.1	Number of presenting eligible patients, number of completed questionnaires and number of hospital admissions per month	213
B4.4.2	Type of incident	214
B5.4.1	Grade of doctor by intubating specialty	230
B6.3.1	Map of Scotland: approximate geographical boundaries of the area covered by the Institute of Neurological Sciences, Southern General Hospital, Glasgow	241
B6.4.1	Pre-hospital times (all patients)	249
B6.4.3	Destination from emergency department	251

List of Tables

A7.1.1	GP responses	124
A7.7.3	MCS and PCS compared to populations norms	146
A7.8.2	Patient or control DEPCAT score	147
B1.4.1	Mechanism of injury of patients with head injuries and associated CSI	184
B1.4.2	Definitive diagnostic source of CSI	185
B1.4.3	Complete, incomplete & transient cord syndromes	186
B1.4.4	Cord syndrome by injury severity score	187
B3.4.1	Mortality of intubated trauma patients in Scotland 1999-2002	204
B5.4.1	Patient characteristics of the two intubating specialties	228
B5.4.2	Matched trauma RSI results	231
B5.4.3	Complications by intubating specialty	232
B6.3.1	Scottish and study populations	242
B6.3.2	Scottish Ambulance Service ORCON population banding: definitions and response time targets	243
B6.4.1	Distribution of trauma patients between urban and rural groups	247

Glossary

A&E	Accident and emergency
AIS	Abbreviated injury score
CHIRPP	Canadian Hospitals Injury Reporting and Prevention Program
CSI	Cervical spine injury
CSO	Chief Scientist Office, Scottish Executive
CT	Computed tomography
DGH	District general hospital
ED	Emergency department
FCI	Functional capacity index
FIM	Functional independence measure
FLP	Functional limitations profile
GCS	Glasgow coma scale/score
HEMS	Helicopter emergency medical service
HI	Head injury
ICD	International classification of diseases
ICU	Intensive care unit
IIS	Injury impairment scale
ISS	Injury severity score
MAIS	Maximum abbreviated injury score
MCS	Mental component score
MRI	Magnetic resonance imaging
MVC	Motor vehicle crash
NHP	Nottingham health profile
NFS	Not further specified

ORCON	Operational control
QWB	Quality of well being
PCS	Physical component score
Ps	Probability of survival
RSI	Rapid sequence induction/intubation
RTA	Road traffic accident
RTC	Road traffic crash
RTS	Revised trauma score
SCPMDE	Scottish Council for Postgraduate Medical and Dental Education
SF12	Short Form 12 (12 items)
SF36	Short Form 36 (36 items)
SIDS	Sudden infant death syndrome
SIP	Sickness impact profile
SPSS	Statistical Package for Social Sciences
STAG	Scottish Trauma Audit Group
TARN	Trauma Audit and Research Network (England & Wales)
TRISS	Trauma and Injury Severity Score
UK	United Kingdom
UKTARN	New name for TARN (see above)
US	United States
WHO	World Health Organisation

Personal statement and structure of MD thesis

My personal progression from a complete research novice to an academic emergency medicine specialist reflects to a significant degree the ongoing progress of the specialty of emergency medicine in the UK as the specialty continues its local and global journey towards improving emergency care for all.

Emergency medicine is a relatively new specialty in the United Kingdom (UK) and indeed globally, with the specialty formally beginning life in the UK as the Casualty Surgeons Association in 1967. The Platt Report (Standing Medical Advisory Committee of Central Health Services Council 1962) confirmed what many had suspected, that 'Casualty Departments', as emergency departments were then known, were often run by surgeons or physicians with no specific interest in the department but who were required to oversee its work. Clinical standards were low, morale was poor, and training was usually non-existent for doctors and for nurses.

The Platt Report recommended the appointment of three orthopaedic surgeons to oversee the management of each department (emergency medicine as a separate entity did not exist at that time) and suggested a change in the name of departments to "Accident and Emergency Departments" to discourage patients from attending with trivial conditions.

In 1972, the UK Government, in response to increasing concerns, sanctioned the appointment of the first cohort of "Consultants in Accident and Emergency Medicine", with a total of around 30 posts around the country. The improvement

in standards and morale was such that continued expansion of the specialty has continued to this day, and the 'gatekeeper' function of the department has increased enormously since then given the increasing attendances and demands from decreasing out-of-hours community medical care in the UK.

Trauma has always formed a large part of the workload of emergency departments, and unlike the United States (US), where trauma became an exclusively surgical specialty; in the UK it has remained multidisciplinary but is often coordinated by emergency medicine specialists (Royal College of Surgeons of England, 1988). While patterns of trauma have changed over time, the need for emergency departments to provide an effective and timely resuscitation service for trauma patients remains steady.

The initial management of major trauma is a daunting prospect for many medical and nursing staff, and emergency departments also play a central role in training both their own staff and surgeons, anaesthetists and other supporting specialties in the care of these complex patients.

I am now a specialist in emergency medicine, with a career long interest in major trauma and its management. After basic training in surgery and emergency medicine in my early career, I felt it would be useful to undertake a clinical research study looking at the outcome of survivors of major trauma in Scotland, and I began to explore the possibilities for doing such a project a decade ago in 1997. An initial review of the literature confirmed the lack of scientific work on this subject at that time in Scotland and throughout the UK.

The challenges here were many: not only was this research area a neglected one but there were no established experts or specialists with significant interest in the topic. This meant there was no track record of research in the field, and therefore funding for such a project was not going to be easy to procure.

A further fundamental issue was that there were no academic emergency medicine specialists in Scotland, although there were local consultants in emergency medicine working as full time National Health Service staff who were enthusiastic, but had no formal research training and no higher degrees. Thus there was no clinical or research infrastructure into which a potential trainee emergency medicine researcher could easily tap in to.

Despite the challenges, trauma outcomes was a subject that I wanted to look in to, and therefore I embarked upon the processes required to get a clinical research fellowship, and therefore funding, and training in the field for this type of research. Despite the support that was forthcoming, particularly from my supervisors, the journey could be lonely and arduous at times, and clinicians and researchers from other specialties often questioned the value of an emergency medicine trainee undertaking such research, as it had never happened before.

Being the first clinical research fellow in emergency medicine in the West of Scotland was certainly a unique experience, and it helped me to forge links between emergency departments in the region and between different disciplines as well, such as emergency medicine, public health, rehabilitation medicine, medical statistics, and the national trauma audit organisation in Scotland.

My first application was for a Chief Scientist Office (CSO) major grant in 1999, and it was rejected. Despite this setback, with encouragement from the CSO and my supervisors, feedback from the unsuccessful application was used to shape an application for a CSO/Scottish Council for Postgraduate Medical and Dental Education (SCPMDE) Clinical Research Training Fellowship which was successful in 2000. This allowed me the chance to spend two years in full time clinical research and research training, which was invaluable to my personal development and progress.

I pursued the research fellowship from 2001 to 2003, comprising of a year undertaking a Master of Public Health degree at the University of Glasgow and a year doing a research project entitled '**Long term outcome of major trauma in Scotland**' which is detailed in **Section A** of this thesis. Section A forms the major part of this thesis, including a detailed literature review of this topic, and a description of the difficulties of clinical research in this area.

Between 1999 and 2004, I was a Specialist Registrar in Emergency Medicine in the West of Scotland; I completed a number of research projects, several of which were related to trauma. These projects were all clinical projects which were all performed in addition to the normal substantial clinical workload of a specialist registrar in emergency medicine.

I have included detailed descriptions of six of these projects in **Section B** of this thesis on the theme of '**Aspects of major trauma in Scotland**'. These six studies reflect different aspects of trauma in Scotland, which had not been

examined in detail prior to these studies. They have all been published in peer-reviewed medical journals, as indicated at the start of each section.

The papers cover a variety of trauma topics. The first two papers examined the epidemiology and clinical evaluation of blunt and penetrating cervical spine trauma in Scotland using the national trauma database, which collected high quality trauma data for 98% of patients in the country for over ten years.

Two further papers looked at different aspects of emergency airway care for trauma, which is of major clinical and research interest. One of these studies was a national multicentre observational study which collected data from the seven major teaching hospital emergency departments and showed that the outcomes following emergency physician intubation were comparable to those achieved by anaesthetists and intensive care medicine specialists. This paper influenced UK practice by legitimising the role of the emergency physician in airway care of the trauma patient and filled the large gap in evidence that frequently fuelled the debate between 'opposing' specialties.

The other airway study involved a specific group of trauma patients who are often intubated without anaesthetic drugs, and frequently are reported to have a poor outcome in the field. This study suggested that some of these patients may survive if they are intubated in the emergency department setting, and potentially this group is clinically different from those who are so severely injured that they can be intubated without drugs in the field.

Another piece of work was an observational study of children's injuries in a Scottish district general hospital. Until this work was done, the only injury epidemiology data for Scotland's children came from the two children's teaching hospitals in Glasgow and Edinburgh, which may represent extreme ends of the injury spectrum. Again, this study was difficult to complete as data collection was very labour intensive, but it identified injury patterns sustained by Scottish children and points toward possible contemporary injury prevention strategies.

The final study examined possible differences in trauma outcomes between the urban and rural population in the West of Scotland. This study again used the national Scottish Trauma Audit Group database but focused on prehospital transport and response times as well as trauma outcomes.

Surprisingly, there was no difference found between the two regions, and this study has major implications for the provision of trauma care in rural Scotland and especially the prehospital response and transport systems that may be required based on the epidemiology of trauma in rural Scotland.

Section C summarises the thesis in a **conclusion** and looks to the future of trauma research in Scotland and the rest of the United Kingdom (UK).

Finally, I have provided a complete **bibliography** of the trauma related projects in which I have been involved in Scotland and subsequently in Hong Kong (since my appointment in Hong Kong in 2004) in **Section D** of this thesis.

In bringing these works together, I hope they convey the sense of examining different aspects of acute trauma, its epidemiology and its systems. The topics covered include aspects of airway and cervical spine care (the core of all trauma resuscitations) and prehospital care, and the studies also cover adult and paediatric trauma in Scotland.

They utilise both clinical and epidemiological approaches, while the main study combines the epidemiological approach to the regional trauma database along with a pragmatic clinical study to identify long term outcomes.

The resulting thesis covers many different aspects of acute trauma, but the work relates principally to the outcome of trauma in a functional sense, which is the most important outcome from the perspectives of patients, relatives and the state.

My work in trauma and emergency medicine research in general continues in Hong Kong a decade after it began, although I am now an academic specialist in emergency medicine and I now help to lead a research team as well.

My journey of development and maturation from fledgling researcher to clinical academic has made steady progress and continues, but the important questions to be answered, and the clinical and epidemiological problems that are posed, remain as relevant and valid in Hong Kong today as they did in Scotland in 1997.

Approach to the scientific literature

This thesis is composed of several sections which refer extensively to the medical and scientific literature.

Section A describes the major project that forms the central core of the thesis and therefore the majority of the comprehensive literature review, and the introduction to the concepts and practicalities of quantification of trauma, trauma systems and trauma recovery are dealt with here in a major review of the literature. Literature search strategies are described and selection and bias are also detailed in part of the thesis.

Section B describes six individual trauma studies which were undertaken in Scotland over the period of pursuing this research. They have all been peer reviewed and published, and primarily for the sake of ease of reading, a brief introduction to each study (as appeared in the published paper) has been retained at each subsection rather than bringing them together as one pluripotent and potentially very large review in one section.

The references have all been brought together for all the works referred to in the thesis for convenient ease of reference and are detailed in Section D. Citations are arranged in accordance with the Harvard system of referencing. The literature has been considered up to the end of December 2006 for the purposes of this thesis.

Section A: Long term outcome of major trauma in Scotland

1: Introduction

The global burden of injury is enormous (Murray and Lopez 1997; Krug et al 2000). Trauma remains a major public health issue (Krug et al 2000; MacKenzie 2000; World Health Organisation 2000) and is predicted to increase in importance over the next 20 years (Murray and Lopez 1997; Krug et al 2000).

Injuries have consistently been noted as the commonest cause of death in England and Wales (2005 data) and the United States (US) (2003 data) in the 1-44 years age group (Anderson et al 1988; Hoyert et al 2006; Health Statistics Quarterly Report 2006).

For Scotland, the leading causes of death have changed over time, with accidental injuries becoming less common and suicide becoming the most common cause of death in males aged 15-34 years. Accidental injury has remained in the top three causes of death in the 1-34 year age group in Scotland in 2005 (General Register Office for Scotland 2006).

Worldwide, road traffic crashes (RTC) are predicted to become the sixth highest cause of death and the third highest cause of disability within the next 20 years (Murray and Lopez 1997; Krug et al 2000).

The only useful way to reduce the number of deaths from trauma is to improve methods of prevention (Maconochie 2003). Primary prevention, defined as preventing the incident from happening in the first place (Hijar et al 2000; Maconochie 2003), is the ideal and should be a high priority for all health care

professionals. Much of the success in primary trauma prevention has not arisen from medical efforts, but rather from the ongoing activities of civil engineers (road design), vehicle manufacturers (car safety design) and systems design (through crew resource management and related activities).

Secondary prevention, defined as reducing the effects of trauma on the injured party once the accident has occurred (for example seat belts, air bags etc), will have some beneficial impact on outcomes following trauma (Maconochie 2003) but this is limited and far inferior to primary prevention.

Mortality following trauma remains the gold standard through which trauma services and their effectiveness are judged. This is simply because mortality is a very clearly defined outcome. What is unknown at present is the morbidity and disability sustained by those survivors of trauma. In the UK, there is little coherent research to indicate what form this disability takes, how long it lasts for and what degree of recovery occurs.

The study of functional outcomes following major trauma has received more attention in recent years, but a recent review of disability following motor vehicle crashes commented that despite the growing number of studies, there were wide estimates of the risk of disability (from 2% to 87%) and there were large variations between studies which made interpretation and collation of data very difficult (Ameratunga et al 2004). They made a plea for well designed population based epidemiological studies using validated outcome measures and appropriate comparison groups.

One of the reasons behind these difficulties is the fact that morbidity after trauma is a nebulous concept which defies concise definition. Functional outcome includes aspects of health status, physical functional ability, psychological status, re-integration with the community (which may be intimately related to pre-injury psychological status), impairment and pre-morbid personality. All of these dimensions and more will play a role in the determination of an individual's outcome.

Nearly three decades ago, the World Health Organisation (WHO) defined outcome in terms of three domains, namely impairment, disability and handicap (World Health Organisation 1980). These terms were updated to impairment (same), activity (disability) and participation (handicap) prior to the start of this study, but the previous terms continue to be used regularly in the literature so both terms and definitions are included for completeness here (Wade and de Jong 2000).

Impairment (unchanged term) is the term used to describe changes in the structure or function of the body, i.e. the original injuries, be they physical or psychological. It is also taken to mean the resulting physical reduction in function that is observed and can be quantified following injury.

Activity (new term), analogous to disability (previous term), is the restriction of ability, or inability, to perform the normal activities of daily living. Activity is therefore a measure of morbidity following trauma and represents the individual's response to their impairments.

Participation (new term) is analogous to handicap (previous term), and represents the disadvantage in a patient's social role, for example return to work status. It is a product of the interaction of the patient's activity (disability) level with the environment and situation in which they are located.

Given these myriad concepts, it is clear that measurement of outcome is even more difficult (Garratt et al 2002). There are literally thousands of different disease specific and generic scoring systems in the medical and paramedical literature, with variable numbers of validation studies and published papers available for each particular system of measurement (Garratt et al 2002).

Major trauma has traditionally been defined as an injury severity score (ISS) of greater than 15 (Boyd et al 1987; Anderson et al 1988). This definition is generally accepted, although alternatives such as ASCOT (A Severity Characterization Of Trauma) and ICISS (International Classification of disease-9 based Injury Severity Score) do exist and have been used in some predominantly US studies (Champion et al 1996; Osler et al 1996).

ISS is used as the basis for many morbidity studies in North America. In the UK, morbidity amongst survivors of major trauma is much less well understood (Airey et al 2001).

This study was conceived and designed to investigate the outcomes of a group of seriously injured patients who survived their injuries and were treated in the Glasgow teaching hospitals. This type of research has not been undertaken in

this group of patients in Scotland before. The patients selected were all victims of blunt trauma (as opposed to penetrating trauma).

The patient group of particular interest are those who have sustained major trauma as defined above but have not sustained a significant head injury.

These patients theoretically should have a good chance of making a good physical recovery if appropriate and timely treatment is administered, given the lack of a significant brain injury.

This study was performed in an attempt to answer some of these questions.

2: Background

2.1: Significance of major trauma in Scotland

UK statistics show that there were 3 409 trauma deaths in the year 2000, along with 38 155 seriously injured patients and 278 719 casualties who sustained slight injuries (Department of Transport, 2001).

The initial reception and resuscitation of victims of trauma is the responsibility and expertise of specialists in emergency medicine (Dollery and Driscoll 1999; Rainer and Smit 2003). Using the Advanced Trauma Life Support system (Dollery and Driscoll 1999), injuries are diagnosed urgently as resuscitation proceeds and an immediate treatment plan is formulated.

This may include emergency surgery, ultrasound or computed tomography scanning and admission to an intensive care or high dependency unit. Following resuscitation, further surgery may be required for limb or other injuries and the patient will then graduate to a general ward for continuing care. In an ideal health service, active rehabilitation would be started at this stage.

Reports have indicated deficiencies in the care of seriously injured patients in the UK over the last 15 years (Anderson et al 1988; Anderson et al 1989). Audit was consequently recommended to evaluate the performance of clinicians when dealing with major trauma (Beard et al 2000).

Trauma audit is based on TRISS methodology (Boyd et al 1987; Wyatt et al 1998). This is an aggregate of the most serious injuries sustained (injury severity score, ISS, made up of the three most severely injured body regions scored using the abbreviated injury score, AIS), combined mathematically with a measure of physiological status on admission (revised trauma score, RTS), to give a probability of survival (Ps) for that individual patient.

2.2: Definition of major trauma

Major trauma is defined internationally as an ISS of >15 (Boyd et al 1987; Anderson et al 1988).

A typical patient with major trauma may have a traumatic pneumothorax (AIS 3, therefore its contribution to ISS is 9), a fractured shaft of femur (AIS 3, contribution to ISS is 9) and multiple abrasions (AIS 1, contribution to ISS is 1), giving a total ISS of 19.

The two UK national trauma audit organisations (Trauma Audit and Research Network, England and Wales; Scottish Trauma Audit Group, Scotland) both collect data on trauma patients until death or survival at 90 days post injury. No data are collected on post injury morbidity or performance outcome due to the lack of a universally accepted data set.

2.3: Morbidity of major trauma in the UK

Long term outcome (generally regarded as more than 12 months) in survivors of significant injury in the UK is largely unknown. Previous studies have concentrated on patients with head injuries and/or multiple injuries at variable times following trauma.

Previous work in the US and UK has concentrated on functional outcomes of survivors and several US studies have looked at quality of life issues.

It may be important to identify any deficiencies in health status (quality of life) or functional outcome (both mental and physical) as this would allow the targeting of services to try to improve functional outcome and health status.

This aspect of trauma care has largely been neglected in the UK until recently (Airey et al, 2001).

3: Literature review

3.1: Search strategy

MEDLINE (January 1993 - July 2006) was searched using the following strategy: {"major trauma".mp OR exp Wounds and Injuries/} AND {exp "Outcome Assessment (Health Care)"/ OR exp Rehabilitation/ OR exp Quality of Life/ OR SF36.mp OR SF-36.mp} LIMIT to English language and Human Studies. This strategy yielded 688 papers.

This was then reduced to {"major trauma".mp} AND {exp "Outcome Assessment (Health Care)"/ OR exp Rehabilitation/ OR exp Quality of Life/ OR SF36.mp OR SF-36.mp}, which produced 41 papers. These were reviewed and the bibliographies of these papers were examined for other relevant papers.

The World Wide Web was utilised as a source of information. The SF36 website (www.sf36.org) and Qualitymetric website (www.qualitymetric.com - the distributors of the SF36 and SF12 questionnaires) were examined. The website of the Health Services Research Unit of the University of Oxford (www.hsru.ox.ac.uk) had useful information on the SF36 from a UK perspective.

The literature review is presented in two parts. Firstly, major trauma studies are considered in various parts of the world, namely the UK, the US and Europe, and in specific circumstances, such as the young and the elderly and those with specific injuries. In researching and then writing this section, I have tried to be as comprehensive as possible for the UK (as it was the focus of this work) and

the US (as it is acknowledged to have the most comprehensive trauma care systems in the world).

For the other sections, space considerations have led me to be more selective in the choice of studies, although I have tried to include studies that are representative of the groups under discussion and studies which are of reasonable quality. This introduces inherent bias, but the sheer volume of material mandates some kind of selective approach.

In the second part, the most commonly used outcome instruments are described and considered in terms of practicality and usefulness to the researcher. It should be noted that there are many more instruments available than it is possible to cover concisely and therefore again a degree of selection has been necessary.

Studies were selected primarily if they were concerned principally with major trauma patients and if they demonstrated important methodological and practical issues about the rating scales under consideration.

3.2: Major trauma

3.2.1: UK studies

In 1970, Gissane commented on the need to assess morbidity following trauma in addition to mortality and showed the high incidence of disability in trauma survivors (Gissane et al 1970). Gissane suggested that disability can have a profound impact on quality of life, although he did not formally measure quality of life, or health status as it is now known. This descriptive study, with no case definitions, was a case series of 4 342 patients treated in a unique "accident hospital". The massive improvements in trauma management over the intervening three decades mean that the paper can only be viewed in an historical context.

Bull (1985) reported a further study of road traffic accident victims treated in the Birmingham Accident Hospital between 1961 and 1980. This retrospective case note review assigned the Bull disability score to patients and compared this with their ISS. This is a simple five point scale which assigns a number to a patient's overall outcome. The Bull score has never been validated and is a very subjective system. One advantage of the Bull score is its inherent simplicity and applicability, but it is likely to be significantly affected by assessor bias and inter-observer variation. Repeatability and consistency have not been assessed in a trauma population for the Bull score. Health status and objective functional outcome were not assessed. While this was a large descriptive study, it had the fundamental flaw of using a subjectively assessed disability rating and this limits the conclusions.

Braithwaite made the first modern attempt to study long term outcome of patients with serious injuries (Braithwaite et al 1998). They studied 158 trauma patients and descriptively measured disability on the Bull disability score. The authors measured outcome at least five years following trauma, although others have suggested that two years following trauma is the optimum time for study as there may be no further improvement after that time (Baldry Currens 2000).

They apparently measured other outcome indicators but the paper did not report any data relating to these. They stated that the Bull score compared reasonably with these other scores. The lack of presented data to support this allied with the inherent flaws of the Bull disability score cast serious doubts over its validity. The disappointing outcomes reported in this study may reflect the measurement methods employed. Their case definition included all major trauma patients, which included patients with head and spinal cord injury. The heterogeneity of this case definition may have led to some of the poor reported outcomes, especially given the known poor functional outcome of many spinal injury and severe head injury patients.

The conclusion that only 30% of major trauma patients make a full recovery should be viewed with considerable caution. The study shows the clear need to define study specific subgroups of major trauma patients to allow conclusions to be drawn about specific injury patterns and mechanisms of injury.

Mkandawire reported the same group's musculoskeletal disability according to anatomical region of injury (Mkandawire et al 2002). This study suffers from many of the problems of the original paper. It reports data from the same

patients (from 1989) and yet is only published in 2002. Given the continuous advances in injury management, the data on clinical management in the paper do not relate to the current options available for trauma patients in 2003.

They continued to use the Bull disability score with its disadvantages. They claimed to have assessed chronic pain using as a subjective ranking system (none, mild, moderate and severe) and correlated that with a 0-10 pain score using a mark on paper, possibly a crude visual analogue scale.

They did not report any data on the pain score or on its correlation with the subjective pain level chosen by the patient. Furthermore they did not define whether the pain score relates to a given anatomical region of injury, or whether it relates to a global pain score; this is important as many patients had multiple musculoskeletal injuries which will influence individual and global pain assessments. The conclusions they draw about the chronicity of pain following musculoskeletal trauma have to be viewed with some caution.

Hetherington reported the use of the functional independence measure (FIM) for the follow up of patients treated in the Royal London Hospital after being transported by the Helicopter Emergency Medical Service (HEMS) (Hetherington et al 1995). It recommends the use of the FIM for trauma patients but presents no alternative scoring systems for comparison.

They state that a small amount of active rehabilitation is afforded to major trauma patients in their centre, but crucially they do not answer the question they pose: does increased or improved rehabilitation improve functional

outcome in trauma? Ultimately this is an unanswered question in the trauma literature, and a well designed randomised controlled trial of standard care versus specific, targeted rehabilitation will be the only scientific way to fill in this important gap in current knowledge.

Baldry Currens and Coats (2000) studied disability in an unselected series of trauma survivors who were treated by HEMS in London. They utilised the Glasgow outcome scale (GOS), which is designed to assess functional outcome post head injury (Jennett and Bond 1975) and the functional independence measure (FIM) at 3, 6, 12 and 24 months following trauma. Their conclusion that assessments of functional outcome should be done 12 months after injury, when there are no further statistically significant changes in detectable function, is flawed.

Firstly the GOS was designed to assess the functional outcome following significant head injury. It is well accepted that there is a ceiling effect and lack of sensitivity at the more functional end of the disability spectrum. It is a fairly subjective scoring system and suffers from similar drawbacks to the Bull score (subjectively assessed global outcome measure). However, like the Bull score, the GOS is simple to apply and readily applicable. The GOS has been studied much more than the Bull score, and inter-observer variability and repeatability do not seem to be a significant problem for the GOS.

Secondly the fact that there are no statistically significant differences after 12 months may reflect deficiencies in the measuring system rather than a lack of

improvement in the patient, namely a ceiling effect. This means that it is poor at identifying minor (but possibly important) functional difficulties.

The appropriateness of using the GOS for this global assessment is questionable given that only 28% of patients had a significant ($\text{AIS} \geq 3$) head injury. The assumption made in this paper is that once the system of assessment cannot identify further statistically significant change, then assessment becomes worthless and should not be done. The alternative view, that a more sensitive assessment should be employed, is not considered.

In a further paper, Baldry Currens (2000) recommends that the FIM, GOS and return to work status should be used as standard indicators of disability after trauma despite there being little objective basis for these measures alone to be the gold standard. The study shows that FIM is relatively sensitive to changes in functional outcome in major trauma patients and that return to work status is intuitively a useful surrogate for functional recovery.

Hetherington and Earlam (1994) also suggest the use of the FIM for disability measurement. Their literature review indeed suggests that the FIM is a useful measurement tool to quantify functional ability.

Haboubi and colleagues reported in 2001 on their experience of assessment of adult patients with minor head injury from 1993 to 1999. It is not clear what constituted a "minor" head injury, but in essence there were high rates of non return to work at two weeks following injury (56%) and at six weeks (8%). These were due to subjective problems such as fatigue, headache and dizziness.

While the current study excludes significant head injury patients, nonetheless, it is possible that because of the way major trauma is defined, some may have a minor head injury (AIS for head =1), and therefore it is important to take into account the possibility that some of the patients in the current study may have symptoms such as those described which are attributable to mild head injury. Furthermore, they postulate that these post-concussive symptoms may contribute to a delay in return to work for these patients, which is also relevant.

Barker and Power (1993) reported on the role of injuries as a potential cause of disability in young adults (age 16-23 years) in the UK. This study used a unique epidemiological design, utilising the 1958 cohort of the National Child Development Study to ascertain the prevalence of disability due to injury since the age of 16 years. The sample size was large, 12 537 subjects, which was an impressive 76% of the original cohort size. There was a higher incidence of disability causing injury in men than in women, and more than 30% of injuries were caused by road traffic crashes.

Perhaps the most significant finding of this study was that more than 50% of men and nearly 75% of women reporting permanent disability from injury had not been admitted to hospital for treatment of their injury. This previously unreported result suggests that any hospital based system for identifying patients for post trauma morbidity studies will at best determine the ability (disability) level of 50% of men and 25% of women.

It appears in light of these findings that the findings of all hospital or trauma registry based studies may only be the tip of a very large iceberg of disability in the community at large. The question that remains is whether or not those disabilities are clinically important and also important to society at large, as no data are presented on work status or receipt of state benefits.

Airey and colleagues reported in 2001 on a cohort of survivors of major trauma from the former Yorkshire Health Region in England. In a well designed study, they used the Office of Population, Census and Surveys (OPCS) UK national survey of disability questionnaire to follow up 304 patients (injured in 1988-89) five years following injury.

They also used the SF36 and correlated the subscales with the OPCS questionnaire domains. They received approval from 15 local research ethics committees and had no need to go through a multicentre ethics committee when the study was planned. The results were not reported until 2001, a significant delay.

Their main findings were that there remains a high prevalence of disability at five years, and that the majority of disability resulted from neurological and orthopaedic injuries. They based their assessment solely on questionnaires and a face-to-face interview, and did not include a clinical assessment at any stage. The strengths of the study result from the high response rate (84%) and the cohort design. The principal weaknesses arise from the use of subjective measures only and the delay to reporting the results.

The same group reported further results from this cohort study in 2003 (Evans et al 2003), concentrating on those who were aged between 11 and 24 years of age at the time of trauma, and therefore were 16-29 years of age at the time of follow up, defined by them as "young adults".

Again, they reported that there was significant disability in this group, with a high prevalence of difficulties with participation: 54% had problems with work and 28% had difficulties in looking after the home. Young adults are an important group in trauma outcome as they are common victims of trauma and have the longest period of time to pay taxes if they recover, or to be financially supported by the state if they do not. The authors' call to investigate the factors underpinning the differences in outcomes is welcome and necessary.

Mason and colleagues reported in 2002 on the differences in outcomes between patients injured in the workplace and those injured outwith the workplace. Again, this was a well designed single centre cohort study conducted in Sheffield, but was restricted to men of working age only. They were prospectively followed up at 6 weeks, 6 months and 18 months following injury. Interestingly, patients who were injured at work were more likely to start legal proceedings and develop symptoms of posttraumatic stress disorder. Patients who did not return to work suffered more psychological morbidity.

Patients were offered a financial incentive of £10 to complete the follow up questionnaires, which is quite unique in the UK. It is interesting to postulate how the approving ethics committee viewed this method, but approval was indeed given. They used the SF36 questionnaire along with various other psychological

assessments for follow up. The authors felt that there was no evidence to support the concept of "compensation neurosis" as an explanation to slow recovery when litigation was ongoing, and yet they postulated that legal action may itself be deleterious to recovery in some cases.

The findings suggest that there may be a protective effect of employment, that is to say, that rapid return to normal work may reduce physical, social and psychological symptoms. The findings of this study, and this specific hypothesis, would obviously need to be tested further before it was fully accepted.

In 2006, Redmill et al reported on 12 year follow up of a cohort of major trauma patients from Northern Ireland. They used a stratified random sample of patients who had sustained major trauma and followed them up at the 12 year stage. No details of ethical committee approval are given. The investigators contacted the patient's GP to ascertain details of disability (measured using the GP's estimate of the GOS), employment status (according to the GP) and details of ongoing medical attendances at hospital or GP. None of this information was obtained from the patient directly except in a few instances where the GP could not provide any information.

The use of a GP as a proxy is unique and questionable. It is possible that the GP would know if the patient is in employment, but if the patient has made a good recovery and never visits the GP, the GP will assume the last employment status of the patient is still true and there may be no correlation. The authors state that they felt that "data from one source was entirely accurate" which

implies a great deal of faith in their information sources, which may be unwarranted.

They also state that return to work rates are as high as 90%, but do not take account of those who have retired and are still active, which is important as the population becomes increasingly elderly. Indeed, they then go on to state that the unemployment rate in those survivors of working age is 34%, but this includes those who were injured as children and are now of working age at this follow up time.

However, given that only 13% of this group was unemployed before their trauma, it is more likely that the 90% return to work rate is inaccurate. Over three quarters of patients made a good or moderate recovery on the GOS, which is encouraging.

The authors do not give details of the type of trauma sustained (blunt or penetrating), mechanism of injury (MVC, assault, fall) or other data that would allow more meaningful analysis. This lack of further information and analysis is disappointing and significantly reduces the value of what would otherwise be a potentially very useful paper.

3.2.2: North American studies

Rhodes studied the outcome of 445 trauma victims transported to a single trauma centre (Rhodes et al 1988). They used the GOS to assess outcome, stating that the practicality of the GOS was of benefit in these circumstances. This descriptive study focussed on patients transported directly to the centre by helicopter. This means that they were likely to be private patients which may partly explain the good overall outcome seen.

MacKenzie assessed the factors influencing patients' return to work following trauma (MacKenzie et al 1987). They studied a large cohort of trauma patients treated at two trauma centres for 12 months. This well performed study correlated variables related to ISS, education and previous work with return to work status one year following trauma using logistic regression. Personal income, educational level and a strong social network were correlates of returning to work. They crucially suggested that social, personal and economic factors play important roles in post trauma recovery.

Holbrook, reporting from San Diego, utilised the quality of well being (QWB) score to assess functional health status (Holbrook et al 1998). They found it a useful and sensitive score compared to a score measuring the activities of daily living. Poor scores at six months were associated with post injury depression, post traumatic stress disorder, serious limb injury and prolonged hospital stay.

A limitation of the study is the derivation of the pre-injury QWB score after the injury occurred. It is possible that there is significant bias in the generation of

that score in the immediate post injury phase. This may accentuate the change in QWB at six months following trauma, if the pre-injury scores are reduced by the morbidity experienced after the injury. Alternatively the post trauma suffering might exaggerate the patient's assessment of their pre-injury status. These factors may introduce a systematic error.

Brenneman used the SF36 to identify which survivors of major trauma, without an incapacitating head injury, returned to work (Brenneman et al 1997a). About half of all survivors returned to work: they were likely to be young professionals with a lower severity of injury. They comment that under 50% of all eligible patients were included, which clearly introduces bias, but accurately reflects the difficulties of studying these patients. The study confirms the practical difficulties of following up predominantly young mobile individuals.

Brenneman also studied the long term (mean of 4 years) outcome of a specific group of major trauma patients with open pelvic fractures using the SF36 and the FIM (Brenneman et al 1997b). Chronic pain, residual disability and unemployment are common outcomes following this devastating injury. The SF36, while well validated, has been used in several trauma follow up studies and yet the normal for trauma patients is unknown. They used the SF36 and the FIM by telephone assessment, although these scores had not been validated for the use by telephone at the time of the study. The FIM was thought only to be reliable when calculated by a clinician directly observing the patient, although a specific "Fone FIM" has now been developed (Smith et al 1996; Chang et al 1997a; Chang et al 1997b, Petrella et al 2002).

Richmond et al (1998) reported on a prospective longitudinal three centre study which attempted to identify predictors of severe disability at three months after 'non-central nervous system trauma'. Their sample was skewed by the very high proportion (33%) of 'violent injuries' patients, meaning victims of gunshot wounds, knife injuries or blunt assaults. This is clearly very different to most other published studies, in which motor vehicle trauma (35% in this study) features in 60% or more of cases.

They had a 46% refusal rate, and studied 109 patients in total. The study utilised the sickness injury profile (SIP), a commonly used system for trauma follow up in the US, and the social support questionnaire, administered by telephone, to gather data. Their findings, that severe disability at three months was associated with a limb being the worst injury (site of maximum AIS score), psychological issues ('intrusive thoughts') and low educational ability, are not surprising. Similar to other studies, this study gathered data on pre-injury data immediately after hospital admission, which raises the important question of recall bias: patients are more likely to exaggerate (either for better or poorer) their pre-existing physical and mental conditions in the presence of a new injury, possibly leading to a systematic error.

The study confirms that the presence of an extremity injury as the principal injury is associated with higher disability levels at three months, which is consistent with previous work by Holbrook et al (1998). Holbrook used a different assessment and scoring system (QWB), so the same finding with different assessment systems in differing populations would suggest that the results presented are a true finding. Richmond also paid their participants

US\$10 after data collection was complete, with full ethical approval, similarly to Mason et al (2002) in the UK.

MacKenzie et al (1998), probably the leading US researcher in the field, reported specifically on aspects of returning to work following injury. They examined a cohort of 312 patients, all treated at three level 1 (i.e. the most sophisticated) trauma centres for a lower limb injury, for 12 months to identify how many returned to gainful employment. They excluded patients with a major central nervous system injury and their follow up rate was an impressive 91.5%.

The vast majority of the injuries resulted from motor vehicle trauma (75%) and high falls accounted for another 17%. They used the AMA impairment score to rate impairment and they assessed return to work status at 3, 6, 9 and 12 months following injury. They used a Cox proportional hazards regression model analysis to estimate the contributions of risk factors for not returning to work in the presence of pain and impairment, a powerful technique to eliminate bias assuming the variables have been assessed accurately.

There was a very strong relationship between impairment levels and return to work status. Other factors associated with a return to work included higher education levels, higher levels of social support, white collar job, and high income. Absence of alcoholism was also a favourable factor. Interestingly, but not surprisingly, there was a negative impact on return to work status in patients receiving 'worker's compensation' and involvement with legal proceedings.

This excellent study confirms that many of the factors influencing return to work are outwith the control of any rehabilitation program, but that the fundamental aspect, namely level of impairment (and therefore the nature and severity of the injury sustained) is the crucial factor.

Michaels used multiple logistic regression analyses to evaluate the outcome of trauma patients without severe head injury at 6 and 12 months following injury using the SF36 and the sickness impact profile (SIP) (Michaels et al 2000). The SF36 showed the loss of physical function and physical role in patients with extremity fractures. This study can also be criticised for relying on gaining pre-injury health status information post-injury. This introduces recall and situational bias, but they point out the baseline values for the SF36 were close to those of the uninjured US population. They concluded that outcome after trauma was closely linked to mental health outcome, although worse outcome was linked to poor pre-injury mental health.

Greenspan and Kellermann reported in 2002 on the physical and psychological outcomes of gunshot victims in a US trauma centre. They were assessed eight months after discharge using the SF36 questionnaire and return to work status. The results are limited in terms of their applicability to a Scottish population, given the relative lack of gunshot injuries and the fact that the population consisted of predominantly male African Americans around 30 years of age. However, the study did show that patients had decreased levels of physical and mental function compared to pre-injury and were suffering from symptoms of posttraumatic stress. One patient in their study could not be re-interviewed at eight months as he had been killed by a further gunshot wound by that time!

Although this study can be criticised on the basis of using a pre-injury SF36 which was assessed post-injury, the authors took the prudent step of also using US norms and their analysis was robust to that. Again, they were not permitted to use financial incentives for their study to encourage participation, but subsequently they were allowed to use incentives, and gave US\$30 for participation. They speculate on whether it may have improved recruitment (25% refused to participate) and it may be a strategy worth considering in future UK studies to improve participation and completion rates.

Cheatham and colleagues reported in 2004 on a small group of patients who had had major abdominal trauma and had their abdomens left open at the end of surgery to prevent or treat the development of abdominal compartment syndrome, where the pressure within the abdomen rises to very high levels and causes gut ischaemia, renal impairment and failure, and respiratory failure. Abdominal compartment syndrome is likely to become more common in the future as more critically injured patients reach hospital alive with improved prehospital care, therefore it may be relevant to a UK population in the future.

Follow up was not good (only 30 patients completed the study from 223 potential patients at one institution) and the authors were not permitted to telephone prospective patients by their ethical committee, so they had to contact them by letter. They also measured SF36 scores and compared them to the US norms, which suggested that their patients have a low quality physical summary score when the abdomen remains open (covered by the time of

discharge with a split skin graft only), but once definitive fascial closure is performed, this returns to the US normal.

The mental summary scores were at the lower end of the 95% confidence interval for the mean normal US mental scores, but there were no statistically significant differences. The study is hampered by the lack of numbers and hence power, but the prospective study they state is currently in progress may shed further light on this interesting group of patients. It is clear that ethical issues are also a problem in certain parts of the US as well as in Europe.

3.2.3: European studies

Maurette and colleagues reported a French study of 1005 patients from a single centre, with a follow up rate of around 65% (Maurette et al 1992). The study group had a mean ISS of 10.5, corresponding to a moderately injured cohort. They specifically studied impairment, disability (now ability) and handicap (now participation) but reported the percentage of patients in which at least one of these factors were present, rather than the level of impairment or ability or participation experienced by the group.

They studied the patients at six and twelve months, and concluded that minor trauma was "fixed" by twelve months, but acknowledged that major trauma was not. This concurs with other work which suggests that functional outcomes continue to improve for at least two years following trauma (Baldry Currens 2000; Van der Sluis et al 1995). The authors indicated the practical difficulties of

measuring the three domains of impairment, disability and handicap, and suggested standardisation of assessments to allow comparisons to be made.

Van der Sluis and colleagues presented an excellent study from the Netherlands in 1995, reporting on a cohort of 723 multiply injured major trauma patients from a single major trauma centre (Groningen). They were severely injured, with a mean ISS of 30.1. Over a quarter of the cohort died shortly after admission, mostly from severe head trauma. They used the GOS as their measure of functional outcome, and did not discuss the drawbacks of the scale as a single global indicator of function. The strengths of their study include the very high follow up rate, with complete data on 98% of patients, and the repeated measurements of the GOS over a two year period.

They did not indicate who did the assessments of GOS, or whether they were recorded by the same individual or different persons. They also did not mention whether or not they required or got ethical approval for the study, and they did not mention consent for the patients. Although not explicitly stated, the patients in the paper seem to be drawn from the institution's trauma registry, and this study shows the strength of such an approach in terms of the completeness of their data and the ability to show changes in function over time.

Not surprisingly, their results showed that functional outcome improved considerably in the first year after trauma, and slowly but appreciably thereafter. They also demonstrated effectively the relationship between ISS and GOS at two years after trauma, with a proportional effect (higher ISS, more disability as evidenced by the GOS). The approach used in this study could be used as a

model for future longitudinal clinical studies of trauma survivors given its very high follow up rate and high quality data.

Anke and colleagues, reporting from Scandinavia in 1997, studied outcome in 69 survivors of major trauma (70% of their original cohort). Despite a high prevalence of residual impairment (80%), disability was rare and return to work was normal (81%). They concluded that individualised plans for patients following multiple trauma may improve outcome.

Lehmann et al (1999) reported on the long term outcome (at least two years following major trauma) of a cohort of severely head injured patients. Their group was young (median age 24 years) and severely traumatised (median ISS 34) with multiple injuries. The presence of severe head injury in the group makes this study less relevant to the current study, but once again there is no mention of ethical approval or consent within the paper, suggesting that consent was not a major issue for the study at the time.

The important result from the study is the lack of impact on long term outcome of chest and abdominal injuries; almost all the residual impairment and disability arose from the extremity injuries and head injuries sustained. The study's conclusions, that intensive rehabilitation would lead the effect of being "better reintegrated in their occupational and social surroundings" is not supported by the data they present. In any case, this would suggest that rehabilitation might improve the handicap aspects of outcome, whereas initial rehabilitation tends to focus upon disability aspects in terms of improving functional outcome. Further clinical studies, in the form of a randomised trial of rehabilitation at different

times following major trauma, would be the only valid way of answering that question in a scientific manner.

Ponzer performed a randomised trial of psychosocial support following orthopaedic trauma in Sweden using the SF36 (Ponzer et al 2000). The case definition was an in-hospital stay of two days with orthopaedic injuries (ISS=5).

It suggested that early psychosocial support may be beneficial in terms of health status after injury. It is very difficult to extrapolate this finding to patients with major trauma given the difference in case definition.

Ristner studied the sense of coherence and lack of control after orthopaedic injuries in 111 Swedish patients one and two years after sustaining orthopaedic trauma (Ristner et al 2000). They showed a correlation between a sense of coherence and all subscales of the SF36. Low sense of coherence, signs of having depression and sense of loss of control over life were correlated with poorer clinical and functional outcome. The mean ISS was 5.7, which limits its applicability to patients with major trauma.

Morris and colleagues, reporting from the Republic of Ireland also in 2000, identified significant disability following trauma and showed that unemployment was common 18 months after injury. The median ISS of 10 indicates that these were moderately injured patients rather than those with major trauma.

Meerding et al reported in 2004 on a large (4 639 persons) postal survey of a national trauma database. They stratified the sample to over-represent injuries

that were severe and those that were less common to allow valid comparisons to be made between subgroups. In contrast to most studies, they also sampled patients who were not hospitalised as part of their treatment, so the sample they used is representative of a national injured population rather than simply a hospitalised population.

They used a European health status tool, the EuroQol (EQ-5D) questionnaire, to evaluate 'functional outcome' (EuroQol Group 1990). In fact, it is a measure of overall health status, not just functional outcome (which is broadly the same as ability/disability). Like the SF36 tool, this postal survey instrument has been well studied and validated in other clinical settings, although this was the first time it had been used on a large population of trauma patients.

Despite the large number of potential subjects, the response rate was 39%, which is low but not unusual for a postal survey. It is likely that the response rate was lower because of the inclusion of patients who were not hospitalised due to their injuries, as presumably their injuries were minor and had largely recovered by the time the questionnaire reached them.

The authors attempted to adjust for response bias and stratification. The principal results, that hospitalised patients reported poorer health status than those not hospitalised, and that their health status (measured with EQ-5D scores) improved over time but were still lower than accepted European norms, are consistent with US studies on similar samples.

They also reported that 10% of their population had not returned to work by nine months after trauma, which is a better rate than many US studies have reported. Again, in common with other work, the body regions that gave rise to the poorest outcomes were patients with spinal cord and vertebral column injuries and hip and other lower limb fractures.

In a related single centre Dutch study, Vles et al (2005) reported on a cohort of major trauma patients as measured by the traditional definition of ISS>15 and entered on to the local trauma registry. 34% died during the index admission or during the follow up period, median and mean of 3.4 years. Follow up was good at 85% of survivors and 26% were dependent on social security benefits as they were unable to work.

Once again, they found that overall health status (using the EuroQol-5D) was poorer than the general population. Worse functional outcome (as assessed by the GOS) was associated with female sex, ISS>25 and number of body regions injured. This is consistent with other European and US studies. The paper did not mention explicit consent and ethics approval. The recommendation, that health status is measured at one and two years following trauma (ideally using both SF36 and EuroQol) is useful.

Ottosson and colleagues reported in 2005 on a study of orthopaedic patients after minor road traffic crashes in Stockholm. From 811 potential patients, only 318 gave consent to take part. Data was collected from hospital notes and from various non-standard questionnaires. Follow up was ascertained only by asking a single question by postal questionnaire about whether or not they feel they

had recovered. Although this can be criticised on many counts (its subjectivity, lack of detail, absolute 'yes or no' value), in many ways it is the ideal question as it is probably the question that is most important to the patient, and maybe their family. This may relate to the low 'recovery rate' at six months, at 56%. The major findings were that education level and work status at the time of injury were the strongest predictors of outcome. The study is only partially relevant to the Scottish study as it focuses on patients with a specific cause of trauma (MVCs) and it has mostly minor and moderately injured patients in the study population.

Another Swedish study, by Sluys et al (2005), focuses on 'major trauma' patient outcome. They used the SF36 questionnaire to assess health status five years following injury, although they recruited patients with an ISS>9 (not ISS>15 as per the definition of major trauma) and the study's median ISS was 14. They achieved a high follow up rate of 83% in a predominantly blunt trauma population. They found that older patients had poorer outcomes in physical terms and that poorer outcomes were associated with longer stays in the intensive care unit and total length of time in hospital.

One very interesting and novel finding was that patients who felt they received poor information from the hospital during their admission had poorer indices of physical health at follow up. If confirmed, this suggests that improved communication during the inpatient phase of care might improve outcomes for patients, in a relatively simple and inexpensive manner. This could potentially be studied in a randomised controlled trial in the future.

3.2.4: Specific types of trauma

3.2.4.1: Outcome after intensive care

Frutiger performed a five year follow up of 233 Swiss patients (Frutiger et al 1991). They included only patients with an ISS ≥ 18 , higher than the accepted definition of major trauma. They used the GOS to assess outcome, although they question its appropriateness for trauma patients. Most patients had returned to work five years after injury. Overall outcome was favourable, especially in those without significant head injury.

Thiagarajan reported an observational study of patients with multiple trauma who were discharged from a single intensive care unit (ICU) (Thiagarajan et al 1994). There was no definition of multiple trauma and no injury severity data were obtained. Whilst the title refers to multiple trauma, all trauma victims who are discharged from the ICU were included.

Follow up was suboptimal, with data being available on only 51% of patients. They measured health status with three scoring systems, of which only the Nottingham health profile had been validated (Hunt et al 1980; Hunt et al 1981). They concluded that health status is poorer than the general population following trauma, but significant doubts on the study's conduct limit its validity.

Mata and colleagues reported on a Spanish single centre study which included all trauma patients admitted to ICU over 1990-1991. Their study had ethical approval and informed consent was apparently obtained for all participants. The authors do not go into any detail on this important aspect as it is likely that most

ICU patients would be unconscious (indeed 25% of them died in hospital), so it is unclear as to whether a surrogate could give consent legally or what procedures they followed.

In any case, this study focused on 'quality of life'. The study is a good example of the confusion that can arise from the use of different terms in different ways by different study groups. Close inspection confirms that their validated 'quality of life score' includes elements of sphincter control (impairment), precise movement capacity (impairment), dependence (ability), and capacity to perform activities appropriate to age (activity and participation). They then go on to discuss 'major handicap', but they actually describe ability (disability) rather than aspects of participation.

Furthermore, they then state that they also checked 'quality of life' by measuring the GOS. The GOS is at best, a global marker of impairment and ability (disability), but it is not a marker of health status overall. They further theorise that, because there is a correlation between their scoring system and the GOS, they are both accurately measuring 'quality of life', which they clearly are not.

This study vividly demonstrates the difficulties of working in this field, and the precision that is required to accurately define and describe the domains under study. The terms associated with these issues (impairment, ability and participation) are not interchangeable and demand clarity.

One other criticism of the study was that they described pre-trauma function as the baseline, by presumably getting premorbid data from relatives for the most

part. This will introduce recall bias (the relative will tend to remember the positive aspects of function rather than the negative ones) and proxy bias, i.e. the data is given by someone other than the patient.

Despite these factors, the authors' findings are consistent with other literature, in that there are improvements in function up to two years following injury and that those with limb injuries tend to be more disabled than those with organ injuries and no limb trauma. Not surprisingly, patients with head trauma tend to have poorer outcomes overall which is in keeping with the literature.

Grotz examined the outcome of 50 patients with multiple injuries and multiple organ failure who were in ICU for long periods (Grotz et al 1997). Follow up was 73% and they selected a severely injured population (ISS>20). They used the FIM and GOS to assess outcome and showed that most patients have a good functional outcome, but that this was not necessarily related to a return to work.

Miller used the FIM and SF36 to assess outcome of severely injured trauma patients (average ISS 29) who survived prolonged stays (more than three weeks) in ICU (Miller et al 2000). 39% of the available patients completed the SF36 which reduces the applicability of the results. Despite good functional recovery, overall health was rated at fair to good.

Dimopoulou and colleagues reported in 2004 on health status and disability one year following trauma in 87 patients who required ICU care in Athens, 74% of all possible trauma ICU survivors. Their cohort was young (31 years) and had a median ISS of 22, a severely injured group. They also used the GOS and the

Nottingham health profile and they also used the Rosser disability scale, a subjective 7 point system for classifying a patient's functional status. They conducted their study by using telephone interviews rather than face to face or postal communication.

Their study comprised almost exclusively of victims of road trauma, and 64% reported physical mobility problems, while around 40% each reported 'energy problems', pain and 'emotional reactions'. Most patients scored 3-4 on the GOS, indicating moderate to severe disability. Interestingly, the multivariate analysis on quality of life (measured by Nottingham health profile) showed that the effect of having a severe head injury increased the odds of a poorer quality of life by 9.3 compared to a minor head injury.

This study was well done and data were collected prospectively; the major criticisms would be the use of a relatively subjective and untried disability scale (Rosser) and the previously mentioned GOS, although their cohort did include head injured patients as well. One year is a short time following trauma, and it could be argued that the outcomes will improve with time in this cohort. Obviously, a repeat study of the same cohort at two years or later would help to clarify the changes in outcome over time.

3.2.4.2: Outcome after lower limb injury

Jurkovich evaluated the use of the Sickness Impact Profile (SIP) in patients with lower limb trauma (Jurkovich et al 1995). The SIP is formed by a physical functioning component and psychosocial score, which has similarities with two SF36 subscales. They excluded the elderly and those with a severe head injury, their definition of which was not consistent with other studies.

They excluded spinal cord injury patients, patients with upper limb injuries and patients with psychiatric disease but provide no specific reasons for this. The inclusion criteria did not include an ISS>15. Their conclusion was that the SIP was a useful tool in the long term assessment of trauma patients.

Butcher et al, in a 1996 follow up to Jurkovich's 1995 paper, showed that most patients with severe impairment following lower limb fracture make a good recovery. However a minority of such patients still have significant disability at 30 months and 18% have still not returned to work.

Mock reported other data from these 302 patients with a unilateral lower limb fracture in 1990 – 91 (Mock et al 2000). Patients were assessed on admission and 12 months following injury and physical impairment scores were calculated along with the SIP. They concluded that only a small amount of the variance of disability was due to physical impairment.

Bhandari et al (2004) conducted a cohort study of 30 patients with an unstable ankle fracture in Canada to evaluate the factors involved in eventual outcome

from these injuries. Once again the SF36 questionnaire was used repeatedly to assess health related quality of life in various domains. Although the study did not utilise a control group, the normative US population data was used as a reference point with which comparisons could be made.

Patients were followed up for two years after injury, and the principal findings were that physical function was significantly decreased compared to US norms, whereas all the other domains remained at or returned to normal. Once again, poor outcome was associated with lower educational status and smoking was also a risk factor for poor outcome. This would be biologically plausible given the prevalence of peripheral vascular disease in smokers and the likelihood of poor healing in a distal site such as the ankle would be higher in smokers.

Alcohol consumption and increasing age was associated with decreased mental function scores compared to normal values. Their conclusions, that social factors play an important role in determining outcome, are consistent with the other studies reviewed.

MacKenzie et al (2004) assessed the functional outcome of different levels of lower limb amputation following trauma in a multicentre prospective cohort study. They used the SIP for the activity (disability) assessment as in previous studies, although it is acknowledged that the SIP contains elements of participation assessment as well. These patients were all treated in Level 1 trauma centres and had either a below knee, through knee or above knee amputation within three months of their injury. All patients who had undergone amputation were severely disabled according to the SIP criteria.

However, patients with a through knee amputation had the highest levels of disability and were much less able to complete a standardised walking test compared to both the above knee and below knee amputation groups. Once again, poor level of educational attainment and smoking were risk factors for a high SIP score reflecting high levels of disability. It is clear from these data that through knee amputations should be avoided if at all possible in patients who require a post-trauma amputation for lower limb injury. It appears that, similar to patients with vascular disease, an above knee amputation is functionally a much better option for trauma patients.

In 2004, Read et al reported on life altering outcomes after lower limb injuries in motor vehicle crashes. They considered both physical and psychological issues in their comprehensive survey, which was restricted to occupants of newer vehicles with modern seat belts and other restraint systems, such as airbags. The numbers were comparatively small at 65, but they showed that patients with fractures have poorer outcomes than those who do not, and that many patients had evidence of undiagnosed mild traumatic brain injury, as evidenced by cognitive decline and symptoms of PTSD.

Of interest, they also included data about pre-injury health status, including the fact that many of the group were obese, diabetic and depressed, despite their comparatively young mean age of 39 years. They speculate that the presence of these diseases or conditions may have had some impact on their driving style or ability and made them more prone to crashes, but in the absence of a control group this can only be regarded as hypothetical.

They make the important point, which is often overlooked by other commentators, that vehicle design is clearly not optimal as these injuries still occur with monotonous regularity and severe injuries are often the result. Vehicle design can potentially make a difference both to victims of trauma within the vehicle, and to those who are struck by the vehicle as pedestrians.

In 2005, MacKenzie and colleagues extended their previous prospective cohort study of severe lower limb trauma to seven years of follow up. This well designed study confirmed that severe lower limb injury is associated with persistent poor outcomes assessed by the SIP, regardless of the mode of treatment (reconstruction or amputation). The number of patients was large, with 569 patients originally enrolled and complete data available on 397 surviving patients at seven years follow up, a remarkable achievement. Poorer outcomes were associated with females, older age, low education attainment, poor socioeconomic status and smoking.

Zelle and colleagues reported in 2005 on a unique study of functional outcome from Hanover in Germany. They examined the impact of injuries below the knee joint in patients with multiple trauma. The unique feature of their study is the long term follow up period, a mean of more than 17 years following injury. They utilised a range of functional outcome tools, most of them very specific lower limb assessment tools, but including the SF12, a shorter version of the SF36.

In essence, they showed that fractures below the knee and complex fracture patterns contribute greatly to poor outcome following multiple trauma involving

at least one lower limb. The study can be criticised for not using 'standard' assessment tools (such as the SF36 or SIP), which limits the ability of researchers in the field to compare outcomes with this study. However, the general findings of the study are consistent with most other literature on the topic although detailed comparisons cannot be made.

Zlowodzki et al detailed in 2005 the functional outcomes, assessed using the SF36 questionnaire, of patients who had to undergo operative treatment for non-unions of lower limb fractures. Non-unions are uncommon complications, but can cause severe long term disability to the patient. This is clearly shown by the low baseline scores in all domains of the SF36 in this study in the pre-operative assessment. All values are below the US normative data.

In the patients who had successful surgery to unite the fracture, all scores improved and this suggests that the treatment had the expected effect on health status. However, despite this, none of the domains reached the US normative means for any of the scores postoperatively, emphasising the work of MacKenzie (above) which indicates that lower limb disability is often severe and long lasting despite the mode of therapy. This study can be criticised on the grounds of small numbers of subjects ($n=230$), but this is a relatively rare condition. Also, the postoperative assessment took place in the clinic, and only once. It may be that postoperative disability levels may have improved further after time had passed, although it is equally possible that function could have deteriorated, for example, due to advancing age.

3.2.4.3: Outcome after upper limb injury

Dowrick et al (2005b) examined the outcomes following major trauma with and without an upper limb injury. This is a neglected area following major trauma, as most attention is (rightly) diverted to the management of life threatening injuries at the resuscitation phase, and efforts to identify and treat upper limb injuries usually follow later. They used the VSTORM (Victoria State Trauma Outcomes Registry and Monitoring) database from Melbourne in Australia, which has data on length of stay, mechanism of injury, age, sex and injury severity data. It did not have data on functional outcomes at the time of this study, and the study group consisted of blunt major trauma patients only.

The numbers were large (n=1051 patients) and they conducted a logistic regression analysis to identify if the presence of an upper limb injury was associated with any outcome measures. This well performed study showed that patients with an upper limb injury were more likely to stay in hospital for more than 7 days but there was no relationship with the type of discharge location (home, rehabilitation, etc).

The authors speculate that this may be due to the increased nursing burden when patients have upper limb injuries, or greater complexity of care, but this must be tempered with the lack of data on specific functional outcome of the upper limb injury and overall health status at the time of injury and discharge. Further work is clearly required to clarify the factors involved in the burden of upper limb trauma in the context of major trauma.

3.2.4.4: Outcome after paediatric major trauma

Van der Sluis et al (1997) used the SF36 and other scores to assess the long term (defined as 7 to 11 years) outcome following serious injury in children. This comprehensive study, which used the SF36 along with other outcome indicators, had an 85% long term follow up rate and showed the significant recovery potential of children after major trauma. There were no differences between the SF36 scores of the injured children compared to a reference population.

Macpherson et al (2003) examined the relationship between mechanism of injury and functional outcome in children (aged 2 to 15 years) in a retrospective cohort study based in Toronto, Canada. They used an ISS of 12 or more to define 'severe paediatric multi-system trauma', which is not the standard definition of major trauma but seems very reasonable in the context of children. They used a paediatric version of the FIM, 'weeFIM', to assess functional outcome at six months after hospital discharge. The follow up rate was an impressive 73% and most children had suffered a central nervous system injury.

Children who had been involved in a motor vehicle crash (either as a pedestrian, vehicle occupant or struck by a vehicle while riding a bicycle) were much more dependent (and had lower functional outcomes) compared to children who were injured at sports or fell from their bicycle (no vehicle involved), despite logistic regression adjusting for ISS, age, and the presence of a CNS injury (which tends to worsen outcome at all ages).

This excellent registry based study clearly indicates the areas in which primary prevention measures for paediatric trauma should be targeted and provides very useful clinical data for those caring for injured children.

Winthrop et al reported in 2005 on a further US based longitudinal registry based study of children aged from 1 year to 18 years. They excluded head and spinal cord injured patients, and selected patients with an ISS>9, thus including both moderately and severely injured patients. They used the child health questionnaire to assess health status and the weeFIM to measure functional outcome. They mention the term 'impairment' in the abstract to the paper, but do not at any stage truly measure impairment, they focus instead on overall health status and ability (disability).

156 children were studied up to twelve months following trauma, and the principal results suggest that although children improve functionally and in terms of overall health status, they do not reach the age related normals that would be expected. Unfortunately, the authors have not reported further progress (so far) and hence it is unclear as to whether or not this will represent the final improvement in health, or whether, like many adult studies have reported, functional improvement will still be possible until two years or more following trauma.

Holbrook and colleagues reported in 2005 on long term psychological outcomes in adolescents between 12 and 19 years of age. They recruited suitably aged patients from their established trauma recovery project in San Diego, excluding patients with severe brain or spinal cord injury. Again, they used the QWB scale

to assess health status and they used a validated scale to assess psychological factors for post traumatic stress. Follow up was good at 89% of all potential subjects, and 27% were found to suffer from post traumatic stress disorder (PTSD). PTSD was associated with various factors, especially death of a family member in the same incident, and low socioeconomic status and drug and alcohol abuse were strongly associated.

This has direct relevance to the Scottish population, where drug and alcohol use in adolescents is not uncommon, and is associated with trauma. They also suggest that PTSD impacts negatively on health status, which is intuitive but clearly demonstrated here. The remaining question, which is not answered in this study, is whether specific treatment for PTSD would improve both symptoms of PTSD and/or health status. Further trials are clearly required.

3.2.4.5: Outcome after major trauma in the elderly

The first problem with discussing the outcome of trauma in the elderly is the definition of elderly. While most UK authorities feel that the onset of being elderly is age 65 years, some studies have defined elderly as >55 years or some other age. Therefore, the actual definitions of 'elderly' need to be determined for each study to ensure that any comparisons made are valid.

Susman et al (2002) studied the mortality and functional outcome of elderly patients (>64 years) who had sustained traumatic brain injuries in New York and compared them with younger patients with the same injuries. Over 11 770 patients were in the trauma database, and elderly people had double the risk of death from head injury compared to younger people.

Even at high GCS scores (13-15), the chances of death were nearly eight times higher compared to the younger group. This suggests that the effects of so-called 'minor' head injury are very much more pronounced in older patients than in younger age groups. Similarly, functional outcomes were poorer in the elderly, which was assessed by looking at three aspects of the FIM score. The strength of this study lies in its large numbers and statewide trauma registry approach to data collection. It could be improved by using a better and more comprehensive functional outcome measure rather than simply examining three small factors from an established scoring system.

Inaba and colleagues reported in 2003 from Toronto in Canada on the functional outcome of elderly patients (defined as ≥ 65 years of age). They used

the SF36 administered by telephone and compared their data to age adjusted normal values for Canada. They did not recruit a control group but their approach allows the researchers to compare to national norms, thus reducing the need for community controls.

They achieved a 75% response rate and they showed a significant reduction in almost all domains of the SF36 instrument, confirming that health status in these elderly patients was poorer than age matched and country specific population data. Mean follow up time was 2.8 years, and 63% were still living independently compared to 98% before injury. This suggests that despite increased physical disability being more prevalent, independent living was possible for the majority of survivors.

Grossman and colleagues (2003) studied the functional outcomes of very elderly patients, defined here as 80 years or older. They compared their functional outcomes (measured using a modified FIM score) with the 'younger' geriatric cohort of those aged between 65 and 79 years. Similar to other studies of trauma in the elderly, falls are the commonest reason for trauma compared to motor vehicle crashes in younger patients. This reflects different patterns of vehicle use in later life and falls probably reflect to some extent the effects of increasing comorbidity as life progresses. This is confirmed by this study, with the incidence of almost all disease groups being higher in the very elderly compared to the younger elderly group.

They again used a statewide trauma registry and studied a total of 43 297 patients over 65 years of age. The strength of this approach is self evident.

Increasing injury severity was associated with increasing mortality, and those aged over 80 had a significantly higher mortality than the younger geriatric group. Functional outcome was statistically significantly poorer for all domains of the FIM score in the very elderly group.

However, social interactive skills and feeding skills appeared to remain as high in the very elderly group compared to the younger elderly group, which gives rise to the difficult question of what constitutes a good functional outcome. If patients are capable of feeding and interacting, even though they need assistance with moving and transferring, that may be considered an acceptable health status for some and unacceptable for others. It is clear that further work is required to clarify what 'acceptable' means in this context, although this is probably a very individual judgement for each patient. It does mean that the very elderly trauma patient warrants full trauma care in the same way as any other trauma patient as the outcomes are fairly good.

Mosenthal and colleagues (2004) performed a multi-centre study of functional outcome after 'mild traumatic brain injury' and examined for outcome differences by age group. The investigators defined elderly patients as ≥ 65 years, but they defined minor head injury as an AIS of 3 for the head region associated with GCS scores on admission between 13 and 15.

This AIS definition includes injuries such as a subdural haematoma, which many UK clinicians would not agree is a 'mild' injury. Indeed, 12 patients in this category required a craniotomy. Elderly patients had a very comparable

outcome compared to younger patients, although they required more rehabilitation and had lower FIM scores at discharge and six months follow up.

Six months is a short time frame to ascertain outcome especially after fairly serious head injuries, and an extended follow up (as suggested by the authors) is surely required to clarify progress in this group. The study does suggest that the influence of a so-called 'mild' injury can have significant effects on recovery.

3.2.4.6: Outcome after major trauma in women

Several studies have examined the outcome of trauma in women, arguing that they will experience significant differences in various aspects of outcome compared to men. McCarthy et al (1995) examined general health status and sexual function in women after 'serious orthopaedic injury', which was taken to mean pelvic or lower limb fractures. They used the SF36 to assess health status, and specific questions on sexual function which were not validated prior to the study. The results, that these injuries cause women to have poorer general health status and specifically with regard to sexual function, are not surprising.

However, the study did suggest that the most significant predictor of poorer outcomes were previous comorbidities, which emphasises the importance of considering pre-injury health status in assessing post-injury health status. One of the significant advantages of the SF36 questionnaire is the ability of the researcher to compare their results to accepted population norms, which

reduces the risk of recall bias when patients or their families are asked about pre-injury health status and function.

Ponzer and colleagues reported in 1997 on a study examining factors influencing recovery from moderate orthopaedic injuries. This study can be criticised on several points: it did not use recognised tools to detect disability, and it arbitrarily specified different domains, which inherently have significant overlap, for example 'social life' and 'leisure time'. Their conclusion, that psychosocial support is required for all injured patients, is not sound based on their results. In any case, such a proposal would be difficult to support on grounds of cost alone, and some patients may refuse such interventions.

Holbrook and Hoyt reported in 2004 from the San Diego trauma recovery project on the impact of major trauma in women. Details of the registry have been mentioned previously, and this registry has produced excellent longitudinal data on trauma outcomes for some years now. The study showed that women were more likely to have poor health status at 6, 12 and 18 months after injury. Women also had more PTSD morbidity compared to men. Again, the next question to be asked has to be: does any intervention on women (as opposed to men) improve these symptoms of PTSD and would they improve overall health status, or is this finding related to pre-injury comorbidity? It appears that the study did not control for previous illness or psychological states, although admittedly this would be very difficult to do.

Sutherland et al (2005) provides data on this topic from the Grampian region of Scotland. They also used the SF36 and two other questionnaires (completed by

the patients and posted back to the investigator) and achieved a 75% complete follow up rate. They examined orthopaedic trauma patients at admission, two months and six months following injury. Importantly, they excluded all patients with significant head injury or alcohol intoxication, which will introduce an inclusion bias into the data. However, their study suggests that there is little difference between men and women with respect to health status after musculoskeletal injury.

They state in their paper that the study needed around 16 times as many patients (3200 v 200) to reduce the chances of a type II error, so the results have to be viewed with caution as they are underpowered to show no difference in outcome. It is intriguing to speculate why these two studies show opposing results. The designs are different (multicentre registry versus *ad hoc* enrolment) and the populations are different, but clearly more research is required to clarify whether or not women have significantly different outcomes compared to men to warrant different approaches to physical or psychological care.

Vles et al (2005) described a difference in outcome between men and women in a single centre Dutch study of major trauma, with women having poorer outcomes overall. The measurement tool for this study was the EuroQol-5D, and the fact that this difference persists despite the use of a new data collection tool suggests that the difference is real rather than a feature of the data collection instrument.

3.2.4.7: The impact of minor head injury

The impact of minor head injury on recovery from major trauma can be significant. Minor head injury is difficult to define, as different studies use different definitions. Many clinicians would use the definition of the GCS being between 13 and 15 points in the emergency department or during the acute phase of their head injury.

However, this can include patients who remain conscious and, for example, have an extradural haematoma requiring neurosurgery. Therefore other studies use an AIS based definition: a head injury is minor if the AIS for the head injury is less than or equal to 2 in the presence of a GCS of 13-15 during the acute phase. For our study, which aimed to include those with 'no significant head injury', we defined this as GCS 15 at all times and AIS for head of less than 2, i.e. 0 or 1.

The UK study by Haboubi et al (2001) reported high rates of non return to work at two and six weeks following injury (56% and 8% respectively). Many of these patients reported subjective problems including headache and fatigue, and these are likely to be amplified in patients with co-existing other injuries.

A major prospective cohort study of recovery following head injury was performed in Glasgow in 1995-1996 and published in 2000 with further follow up reported in 2006 for the same cohort (Thornhill et al 2000; Whitnall et al 2006). This large cohort study was well performed and demonstrated significant prevalence of poor outcome (as assessed by GOS, which is of course more

appropriate in the context of head injury assessment) even in those with minor head injury (defined as GCS 13-15 on admission). Around half of all patients with 'mild head injury' were reported to be disabled at one year following injury.

The follow up report in 2006 suggests that the prevalence of disability does not improve at 5-7 years post injury, and therefore the impact of the so-called 'minor head injury' is much more malignant than was previously recognised. Trauma outcome studies need to account and stratify for all levels of head injury and recognise that even 'minor' degrees of head injury can profoundly influence overall outcome.

3.2.5: Summary of trauma literature

The trauma outcome studies listed are very mixed in their quality and applicability to the UK and Scottish situations. Significant weaknesses include: few (but increasing) UK studies; weak methodologies; variation in case definitions; small numbers, reducing power; inability to divide the overall trauma population into logical sub-groups; limited use of validated scoring systems; massive variation in the use of different assessment systems; and variable methods of consent and inclusion criteria.

There was a lack of high quality studies examining the UK situation at the time of undertaking this study. Although evidence of incomplete information on UK trauma outcomes remains, the situation is clearly improving and there are now a few higher quality studies appearing in the literature, mostly from the US and Europe.

Without question, the best of these studies have used a registry approach to identify and recruit patients and this is a strategy which could be used in any future studies.

3.3: Outcome indicators

3.3.1: Assessment of impairment

3.3.1.1: *American Medical Association impairment scale*

The American Medical Association impairment scale (AMAIS) (Cocchiarella and Andersson, 2000) is an objective assessment of a patient's impairment. It can only be administered by a doctor.

The score is generated following a clinical review of the patient, in person. Patients are asked about every aspect of their physical and mental health, but concentrating on the physical aspects of function. Detailed examination follows, including assessment of joint range of movement (with a goniometer) and specialist tests for assessment of the heart, vision and hearing in selected cases. The AMAIS was designed to be used to facilitate accurate and reproducible comparisons between patients who were seeking compensation, particularly from insurance companies in the US.

It is important to note that these specialised tests cannot be organised or performed at a single outpatient appointment, or if the assessment is performed in the community, for example, at a patient's home. Data from each aspect of the examination and history contribute to the scoring system, which is highly complex and consists of a large hardback book which must be followed to generate an accurate score.

AMAIS leads to the generation of a percentage: a fully able bodied, uninjured person would score 0%, but an individual who has residual limitations of

function will score much more. This allows a robust baseline to be developed for the impairment of patients and controls and allows comparisons with other scores under study.

Previous trauma outcome studies have used the AMA impairment score. It was used by McCarthy et al (1998) to demonstrate the validity of the score for lower limb trauma and it has also been used in MacKenzie et al's 1998 study examining factors associated with return to work after injury.

3.3.1.2: Other scales

Impairment has been the focus of many anatomically specific outcome tools, such as the American shoulder and elbow surgeons elbow and shoulder scales (Dowrick et al 2005a). These tools and other similar instruments often include elements of health status or disability as well although it is often clear which domains are being tested by which sections of the instrument.

The injury impairment score (IIS) was developed by the Association for the Advancement of Automotive Medicine (1994) in the US. It uses a 'dictionary format', similar to that used for the AIS score, to identify a score for a particular level of impairment by functional assessment of individual body regions.

Massoud and Wallace (1996) used the IIS tool to assess patients' impairments in 86 patients with pelvic or lower limb injuries several years following trauma. They also used the SF36 and various self devised assessments to correlate the IIS with their markers of pain and disability. This study had great difficulty in

recruiting patients for various reasons which limits the applicability of the study. The statistical analysis was flawed by the use of correlation only, and no firm conclusions can be drawn from the study. It has been infrequently used in outcome studies since then.

3.3.2: Assessment of activity (disability/functional outcome)

3.3.2.1: *Functional independence measure*

The Functional Independence Measure (FIM) is a reliable and sensitive indicator of functional status (Keith et al 1987; Hall et al 1993; Hetherington and Earlam 1995; Hetherington et al 1995). It consists of 18 items which must be completed by a health care professional in a face-to-face setting. Seven options are available for each item response, as detailed in Appendix 16. Thus the maximum score available is (7x18) which is 126; the lowest is 18.

The FIM has been shown to be valid, reliable and sensitive to change, and it incorporates what the developers of the project felt was the minimum dataset required to properly assess disability in all patients (Hall et al 1993). Despite this, a more limited subset of the FIM was proposed to be used to assess trauma survivors longitudinally, consisting of the three FIM items of eating, walking and expression, with four potential levels of scoring rather than seven (Mortifee et al 1996).

A retrospective comparison of this limited set was performed against the full FIM score, and it clearly showed that there was little correlation, and the limited dataset did not detect any useful changes in FIM and therefore in disability

(Mortifee et al 1996). This would appear to confirm that the full FIM is required to accurately document the disability status and ongoing progress of trauma patients as originally proposed.

It has the drawback of requiring training in its assessment and it has a "ceiling effect" at the more functional end of the spectrum (Hall et al 1996). Small deficits in functional ability which may have a significant effect on the subject's ability to undertake a specific task may not be identified by FIM, but this is a common finding in many disability scoring systems. The FIM and most of the other scoring systems were developed to chart changes in functional ability over the course of medical rehabilitation, and they serve this purpose admirably. They were not specifically designed to identify small but personally important details in functional outcome. Perhaps generic health status measures such as the SF36 are more suited to identify these factors as they often represent subtle interactions between the individual, the injury, family and friends, recovery from that injury and their environment post-injury.

The FIM is however, a good tool to track functional recovery and status over time following trauma. The disadvantages of the need for personal assessment have been challenged in some studies which have trialled the use of a 'Fone-FIM', with good results reported (Chang et al 1997a; Chang et al 1997b). This may remove one of the obstacles to the routine use of FIM in the follow up setting.

FIM has been extended, particularly for use following traumatic brain injury, by the addition of the 12 item Functional Assessment Measure (FAM), which is

always used in conjunction with FIM to form the 'FIM+FAM' score. 'FIM+FAM' has been shown to have high internal reliability and consistency, suggesting it is a useful measure for those with brain injuries in particular (Hawley et al 1999). There is little evidence of its use in general trauma follow up studies.

3.3.2.2: Barthel index

The Barthel Index (BI) was first developed in 1965 as a simple tool to score and document disability and independence (Mahoney and Barthel 1965). Despite its age, it has been one of the commonest indices used in rehabilitation medicine and is regularly used in outcome studies of all types. It consists of 10 items which are scored variably to give a maximum score of 20 and a minimum of 0. It is a reliable and valid tool and has been cited as 'user-friendly' (Wade and Collin 1988).

However, it has been criticised as being too simple and possibly unresponsive to changes in patient's condition over time (van der Putten et al 1999). A comparative study of responsiveness of the BI and the FIM in patients with chronic neurological disease (multiple sclerosis) showed that although there were demonstrable floor and ceiling effects, both scales had good responsiveness to changes in patient's conditions, suggesting that the simpler BI has a continuing role to play in clinical follow up (van der Putten et al 1999).

The FIM is undoubtedly more detailed and allows the derivation of subscales for motor and cognitive function, which may make it more favourable for research

compared to the BI, but the simplicity of the Barthel index makes it attractive as a tool for day to day clinical use.

3.3.2.3: Functional capacity index

The Functional Capacity Index (FCI) is unique in that it was designed specifically to be used for trauma outcome research (MacKenzie et al 1996b). It focuses on the necessary physical activities of daily living and does not include any element of psychosocial health. The FCI examines ten dimensions of functional activity (disability) and generates a single figure summarising the measure along with details of the ten domains studied.

It is concise and takes an average of 8 minutes to complete (MacKenzie et al 1996b), making it attractive for research purposes. It can also be administered over the telephone. It is robust to proxy involvement (i.e. the need for another person to provide data for the individual due to problems with cognition, communication etc). It appears to be acceptable to patients, although some patients object to the questions about sexual function, and MacKenzie (1996b) has questioned the need to retain the question in the FCI.

It is a preference based questionnaire as opposed to a psychometric assessment of functional outcome, and therefore it can be used to assess disability from an economic perspective as well. This is a clear advantage over other measures. However, it is only sensitive to physical aspects of outcome, not emotional or psychological, and caution is required when interpreting its results because of this. It is recommended that the FCI is used in conjunction with other instruments examining health status overall, such as the SF36.

The FCI has been validated for blunt trauma, and appears to be a very useful and promising tool (MacKenzie et al 1996b). A further validation study has recently been published from Australia, suggesting that the measure is robust to different populations as well (Schluter et al 2005). The FCI is evolving as a very useful tool to describe and possibly to predict functional outcome (Schluter et al 2005) in patients with blunt major trauma and as such is promising and worthy of further detailed study.

3.3.2.4: Other measures

Many other measures have been proposed for the study of disability. In the interests of conciseness, the review of the literature has been necessarily restricted. However, two other scales warrant a brief mention.

The Glasgow outcome scale (GOS) was developed in 1975 by Jennett and Bond and remains one of the most commonly used outcome measures for head injury follow up studies today. As noted previously, it has been utilised in several follow up studies of multiple and major trauma regardless of the presence or absence of head injury in these patients. It consists of a five point scale with categories ranging from death to vegetative state, to severe disability, to moderate disability and finally, good recovery.

This score has been criticised on account of its small number of intervals, the subjectivity inherent in the score, and the presence of a significant ceiling effect,

that is, slight disability is often not identified by the score on account of its broad categories. This may cause a perceived lack of responsiveness to change or to continuing recovery (Gabbe et al 2005).

Despite all of this, it has been shown to have excellent inter-rater reliability and is equally good when assessed by telephone or in person in head trauma (Pettigrew et al 2003). The inherent simplicity of the tool is both its strength and its weakness, and it has not been extensively studied in patients without significant head injury. The Bull score (previously described) is remarkably similar to the GOS, and has been studied in descriptive studies of trauma (Bull 1985) but the Bull score has not been formally validated or assessed.

Finally, Barell et al (2002) developed an 'injury diagnosis matrix' which purports to standardise data selection and reports by integrating a matrix of body regions and ICD-9 codes describing the various types of trauma (fracture, contusion, etc.). The importance of this development is not in the direct measurement of disability, but the potential ability to identify patients who are more closely matched in terms of injury location and severity than the current AIS and ISS systems can achieve.

This would allow direct comparisons to be made for specific bodily injury groups using standard injury and diagnostic coding data that are used routinely throughout the developed world. The study presented was merely a descriptive paper, but the group are proposing to examine the systems effectiveness in patients with multiple injuries, which would be the group of most interest. Further developments are eagerly awaited.

3.3.3: Assessment of participation (handicap)

3.3.3.1: *Community integration questionnaire*

The Community Integration Questionnaire (CIQ) was designed to identify the level of integration of patients who have suffered head injuries (Sander et al 1997; Sander et al 1999; Doig et al 2001). It consists of 15 items for completion by the individual or by a family member, with excellent correlation for items regardless of who completes the form (Sander et al 1997). This is clearly very important for patients with brain injuries, but it could also be useful for patients with other neurological issues (e.g. stroke) or those with limb impediments (e.g. spinal cord injury with quadriplegia).

The scoring system appears to be valid and correlates well with other markers of handicap in the brain injured population. Increasing CIQ scores are related to increasing independence and therefore improved community integration (therefore decreased handicap). It has been suggested that ceiling effects are possible with the CIQ, therefore it may not be sensitive to relatively small changes in handicap or integration at the higher end of the functional spectrum (Hall et al 1996).

It has been used in the trauma literature before in the context of traumatic brain injury where it correlated well with other comparable indicators of handicap (Wagner et al 2000). It has not been used in a non-head injured population before and there are no reports of its use in the UK. It is used in the current study as an indicator of handicap, given its simplicity and ease of administration.

3.3.3.2: Other measures

Return to work status has been used by other authors as a surrogate marker of functional recovery (Baldry Currens 2000; Baldry Currens and Coats 2000).

While returning to a different job may not reflect full recovery, the ability to return to the pre-injury occupation is a good indicator of return to a significant level of function.

It may be more useful to integrate the return to work statistic with a measure of readiness to return to work, as many trauma victims are elderly now and have little or no prospect of returning to gainful employment, yet return to a level of functional activity that would have allowed them to return to work if they were younger or if the pension age was higher (as will be the case in the UK in the near future).

3.3.4: Assessment of health status

3.3.4.1: SF36

The SF36 has been used in many generic and disease specific assessments of health status (Bowling 1997). It is well validated, reliable and sensitive to change and it has been extensively used to assess and follow up trauma patients in the past (Lipsett et al 2000). It has the advantage of being completed by the subject and has good reliability (Ware and Sherbourne 1992; McHorney et al 1993; McHorney et al 1994). It can be self completed or completed over the telephone without apparent loss of accuracy or reliability. It appears to be

robust in the scenario of patients with traumatic brain injury as well, facilitating comparisons between brain injured patients and those without brain injury (MacKenzie et al 2002a). It is probably the most widely used generic marker of health status used in the medical literature at this time (Garratt et al 2002).

UK and US specific population means for the major subdivisions and subscales of the SF36 have been published, which allows meaningful comparisons of health status between the group of interest and the general population (Jenkinson 1999). It is easy to comprehend and takes no more than five minutes to complete. It also has the advantage of being translated into many different languages, and most of these variants have been validated in their own context. The US, UK, Swedish and Dutch versions have all been used in trauma studies described in this thesis.

The SF36 is probably the most intensively studied generic health status instrument available. The perceived ease of use of the SF36, coupled with its widespread acceptance and use in the trauma field, make it a highly appropriate tool for data collection for trauma outcome studies. When analysed, it can be divided into eight subgroups to allow comparisons of different domains of health status, and it can also be summarised into a mental component summary (MCS) score and a physical component summary (PCS) score.

The eight different domains are: physical function; role – physical; bodily pain; general health; vitality; social function; role – emotional; mental health. This allows comparisons to be made between studies with respect to these different domains of a specific population's health status which is particularly useful

when comparing subgroups, for example those with spinal cord injury compared to brain injury.

For analysis, the raw questionnaires are scored according to the developer's complex algorithms (Ware et al 1994; reproduced in appendices 20 and 21). Although complex, it is possible to set up an Excel database into which the raw data are entered and the resultant domain scores and summary scores are automatically generated. This was the approach used in the current study and it saves a great deal of time in analysis.

3.3.4.2: SF12

The SF12 is an abbreviated version of the SF36 questionnaire (Ware et al 1996). Perhaps not surprisingly, it contains 12 items for answer rather than 36, and the time for self completion is therefore considerably shorter than that for the SF36. It represents the same eight domains of health status that the SF36 has, and similarly a physical component summary score (PCS12) and a mental component summary score (MCS12) can be generated from the raw data. In general population studies, the summary scores of the SF12 have been shown to be very close to the SF36 (Jenkinson et al 1997). The SF12 is scored in a similar way to the SF36 using SF12 coefficients to derive the summary scores.

Because the SF12 consists of a shortened version of the SF36, the SF12 can be derived from the SF36 without loss of precision. This allows comparisons between the scales to be made rapidly. The SF12 loses precision in some of the domains as the number of items relating to that domain is reduced to one

only, but in reality this does not seem to be an issue if large enough numbers are involved in the study.

The SF12 has been used in trauma previously; the author used the SF12 and the SF36 in a direct comparison of the SF12 administered by telephone with the self reported written SF36 in a previous study (Graham 2002). The intra-class coefficient for the comparison between the telephone and the written versions of the SF12 were 0.89 for the PCS12 and 0.85 for the MCS12, indicating a high degree of coherence between the two methods of deriving the score. This study suffered from small numbers and consequent low power; larger scale studies are required to confirm these findings, but the SF12 could be a useful tool in the long term longitudinal follow up of trauma patients.

3.3.4.3: *Sickness impact profile*

The sickness impact profile (SIP) has been used to assess trauma patients and their health status (Bergner et al 1981). It is not trauma specific, but has been used in several studies of trauma outcome, particularly in the post-intensive care unit setting (Tian and Miranda 1995; Lipsett et al 1998; Lipsett et al 2000).

It consists of 136 items which must be answered, and this is estimated to take between 30 and 45 minutes to complete. This is the principal disadvantage of the SIP, as many patients who are not fully recovered will find it difficult to concentrate for that length of time, possibly even more so in the presence of traumatic brain injury. The 136 items are summarised into 12 categories (equivalent to health domains), and similarly to the SF36, a physical and a

psychosocial 'dimension score' are generated along with a single summary measure (Bergner et al 1981).

Lipsett et al (2000) directly compared a modified version of the SF36 with 20 items (the MSF20) with the SIP in a heterogeneous group of 127 adult patients who had spent a prolonged (defined as greater than six days) stay in the intensive care unit (ICU). These included nine trauma patients. They found good correlations between the two scales at discharge from ICU and at one year following discharge, but agreement was poor at all other time points. They commented that "the tool [SIP] is so comprehensive that it is somewhat laborious for staff and patients" and elsewhere they stated that patients expressed a preference for the MSF20 as it was much shorter.

This suggests that while the SIP may be a comprehensive study tool, it is inappropriate for large scale or repeated assessments of trauma survivors. Another issue is that in a longitudinal study of trauma outcomes, the tools must be acceptable to patients or they will soon stop completing the questionnaires.

Similarly, Lipsett (200) reported that family members were often required to complete the SIP, especially in the early stages in post-ICU recovery, which may lead to subtle but possibly important changes in answers. This is less likely to be a problem in a shorter questionnaire with fewer items such as the SF36 or the SF12 tools.

The SIP is known in the UK as the Functional Limitations Profile (FLP); it differs from the SIP linguistically and it has slightly different coefficients for calculation

of final scores (Charlton et al 1983). It has not been used in the UK under that name for trauma assessments.

3.3.4.4: Nottingham health profile

The Nottingham health profile (NHP) was developed in the UK to provide a system for self assessed health status which could be broadly used across various conditions (Hunt et al 1981). It consists of two parts: the first part consists of 38 items concerning six broad domains, including pain, mobility, sleep, energy, social isolation and emotional state. The second part has seven items on various areas of life, including relationships, jobs, sex and social life and hobbies. The NHP has been prospectively validated (Hunt et al 1980) and it has been extensively used in various areas of health care, particularly chronic diseases.

There are only a few studies on musculoskeletal disorder patients, none of which have a focus on major trauma. Beaton et al (1996) compared the NHP to the SF36 and the SIP and two other measures in patients recovering from musculoskeletal injury. Although correlations between the tools were good, there were significant ceiling effects for the NHP and the SIP, and the authors felt that the different scores gave rise to different impressions of health, which is clearly undesirable.

A further study by Beaton (1997) extended this work and suggested that the NHP, SIP and SF36 had good test-retest reliability (which is clearly important) but that the SF36 was more responsive to self-reported change than the other

instruments. This may suggest that certainly for musculoskeletal trauma (the group known to have poor outcomes in major trauma), the SF36 is more sensitive to change and less susceptible to ceiling effects compared to the NHP, and therefore the SF36 appears to be preferable.

The SF36 also has fewer items than either the SIP or the NHP, which may make it more acceptable to patients and relatives as previously discussed.

3.3.5: Summary of outcome indicators

The available tools for assessment of impairment, activity (disability), participation (handicap) and generic health status have been intensively studied in many different populations of patients as can be seen from this review. The difficulty for the researcher is to identify the most appropriate tools for their particular purpose. This requires an understanding of the aims of the study being proposed, and the intended comparisons that need to be made, either to a control group or to another injury group or to normative data, if available.

For impairment, the AMAIS is clearly the most accurate tool available, but this comes at the cost of complexity and a requirement for personal medical assessment. Activity (disability) scoring is more difficult to determine; the FIM, FIM+FAM, FCI and GOS have all been used in trauma, indeed the FCI was designed for this purpose. All have benefits and drawbacks, but the FIM has been most extensively validated in a variety of trauma populations and hence it was decided to use this for the current study.

The choice is not so great with participation (handicap), although there is significant overlap between the domains of handicap and generic health status as both involve interactions of the individual with the environment in which they are placed, so both the CIQ and return to work status were used as convenient indicators for this study. There are a variety of high quality and extensively studied health status instruments, but none has been as extensively studied and validated as the SF36.

A major advantage of the SF36 is the availability of normative data for the US and the UK general populations, which may allow comparisons to be made without reference to a specific control group. These issues are considered further by Black et al (2001) in critical care follow up scenarios, Revell et al (2003) in the context of trauma, and Gabbe et al (2005) in the situation of considering the most appropriate tools for a trauma registry to use for routine functional outcome follow up in the future. The clear strengths of the registry based approach to follow up and consent are apparent from the literature.

Cameron et al (2006) recently made the case for considering quality of survival as the principal outcome measure after trauma but makes the important point that survival improvements become less likely as trauma systems mature and survival rates plateau. He discusses the difficulties of measuring post-trauma outcomes but also advocates a registry based approach. Preliminary data from the Victorian major trauma system suggest that outcome measurement is feasible and useful, consistent with the conclusions of this literature review.

3.4: Summary of literature review

This review has attempted to demonstrate that major trauma is not only common throughout the UK, US and Europe, but that the quality of the recorded outcomes beyond that of simple survival ('dead or alive') is variable. There is clear evidence that the quality of the literature is improving, particularly in the US, Europe, and Australia.

However, the UK situation remains unclear with significant gaps in knowledge, particularly in Scotland. There is strong evidence to support the selection of specific data collection tools to study aspects of functional outcome after trauma. This study attempts to fill that gap in knowledge by using these tools in a prospective Scottish trauma study.

4: Aims and objectives

The aim of this prospective case-control study was to identify the outcome, specifically by measuring the level of impairment, activity (disability), participation (handicap), generic health status and return to work status of long-term survivors of blunt major trauma (without evidence of significant head injury) in the West of Scotland who sustained their injuries at least two years earlier.

The derived outcome measures were to be compared with control data from a group of age and sex matched patients identified by the patient's general practitioner at the time of obtaining consent from the GP for the index patient to be approached for the study. It used data from the Scottish national trauma registry of the period, the Scottish Trauma Audit Group, to identify suitable patients for the study. Deprivation data was also derived in an attempt to assess any influence from that source.

In common with most other studies of this nature, major trauma was defined as an injury severity score (ISS) greater than 15. A typical patient may have sustained a fractured femur, a pneumothorax and multiple abrasions from a traffic crash. A case-control methodology was chosen to allow a fair comparison of patients' impairments and ability with a control group of age and sex matched control subjects who have not been victims of major trauma. The null hypothesis was that there was no demonstrable difference in impairment, ability or participation, workforce status or deprivation status between the groups.

5: Research questions

1. What is the level of impairment of survivors of blunt major trauma who did not sustain head trauma who had initial treatment in the Greater Glasgow NHS Board area?
2. How does this level of impairment compare to that of an age and sex matched control group drawn from the same community?
3. What are the levels of activity (disability) measured by the FIM of the index and control groups and how do they compare?
4. What are the levels of participation (handicap) measured by means of the community integration questionnaire (CIQ) in the index and control groups and how do they compare?
5. What are the levels of self reported generic health status as measured by the UK SF36 health status questionnaire?
6. How do these health status levels compare between the index group, the control group and normative UK and US data for the general population?

7. What is the current employment status of trauma survivors and how does that compare with the controls? Of those not working, what proportion could go back to work if suitable employment was available?
8. How many of these subjects are receiving state benefits? Are there any links between receiving state benefits and impairment or disability levels?
9. Does deprivation have any part to play in terms of recovery from trauma or return to workforce status?

6: Methods

6.1: Study design and population

A case control study methodology was used. Survivors of blunt major trauma more than two years prior to the study start date (i.e. January 2001) were identified from 223 potential participants in the Scottish Trauma Audit Group (STAG) database. Only those with no significant head injury were included. No significant head injury was defined as a Glasgow Coma Scale (GCS) score of 15 on admission and no or minimal anatomical head injury (i.e. abbreviated injury scale score for head region < 2).

Only anonymised data were held at the STAG central office on trauma patients. Therefore STAG codes were de-anonymised at the four participating hospitals to identify potential participants.

Potential patients were defined as those patients who had initial hospital treatment in Greater Glasgow NHS Board hospitals. Our original research plan was to select a random sample of the group, but difficulties in ethics and recruitment prevented this.

A matched comparison group who had not been victims of major trauma were identified from the registers of the General Practices from which the study group was drawn.

Informed consent was sought from each potential participant's General Practitioner (GP). If the GP gave permission to approach the patient, an invitation letter was sent to the GP for signing and forwarding to the patient (in a stamped envelope sent by the researcher with the letter), in accordance with ethical requirements.

Individual patients then had the option of telephoning the researchers to discuss participation or of simply agreeing or declining to participate. A pre-printed response form and reply paid envelope were enclosed to maximise responses.

GPs were also asked to nominate two age matched (± 5 years) and sex matched controls from their practice lists. Two names were requested to maximise the chances of recruiting controls for each patient. An invitation letter was prepared for each potential control which was sent to the GP for signing and onward transmission to the patient in a stamped envelope. The letter explained the nature of the study and requested participation; response forms and reply paid envelopes were enclosed to maximise responses. The ethical committee stated in a response to us that it was not ethically acceptable to approach patients or controls more than once if no response was received.

Once informed consent was obtained from the GP and the participant, the SF36 questionnaire, the CIQ and a work status questionnaire were mailed to the participant for completion prior to the researcher's visit. STAG provided details of injuries, ISS and length of hospital stay directly to the researcher in the form of an anonymised database.

Patients could be interviewed at home or at hospital, depending on circumstances and preference. We aimed to minimise exclusion bias by not insisting that potentially disabled survivors (or controls) came to hospital when they were not physically capable, or not emotionally ready to return to a hospital environment, perhaps after prolonged or painful treatment.

The researcher visited the homes of the participants who opted to be seen there with a chaperone. A structured interview was conducted with the participant and/or a close relative or friend to elicit details of injuries, previous ill health, work status, current health status, functional independence (FIM score) and physical impairment (AMA impairment score).

A standard impairment proforma was completed and a limited physical examination was performed to allow calculation of the impairment score. The SF36 health status questionnaire was checked by the researcher and any queries were addressed. Similar procedures were followed for the CIQ and work status questionnaire.

Some participants were interviewed at the Southern General Hospital and reasonable travel expenses were paid to patients for this. Nursing staff acted as chaperones.

6.2: Funding

An application for a Small Grant from the Chief Scientist Office of the Scottish Executive was submitted as part of the author's clinical research training fellowship. This was successful in attracting funding of £12 000 (grant number CZG/2/95). This was predominantly used to pay for stationary, postage and cost of chaperones. In addition, a licence fee was required to use the SF36 health status questionnaire. The author's salary was funded by the Clinical Research Training Fellowship from the CSO and SCPMDE during 2001-2003.

6.3: Sample size calculation

The original research proposal was to recruit 80 cases and 80 matched controls. The justification for this was that this could be accomplished in the one year research fellowship timeframe, and in the absence of any pilot or raw data, it was the best estimate at that time. In addition, it was agreed that 80 patients in each group would allow reasonable statistical analyses to be performed and give meaningful results. The research proposal provided for an interim analysis with 10 cases and 10 controls to allow a formal power calculation to further inform the study design.

Discussions had taken place between the project supervisors, the author and Dr Alison Spaul (Director, CSO), along with Ms Jennifer Waterton (Research Manager, CSO), and these target figures had been agreed. MREC subsequently restricted us to 20 cases and 20 controls as a pilot study and

wanted to see an analysis at that point prior to the project proceeding further. By this stage (July 2003), issues of time were very pressing given the fact that the end of the formal fellowship was September 2003. It was reluctantly agreed with CSO to restrict the numbers to 20 cases and 20 controls.

Recruitment proved to be difficult and eventual study numbers were much less than had been hoped for.

Post study power calculations show that the study ($n=19$ for cases, $n=7$ for controls) had a power of 0.853 to identify the observed difference in impairment and 0.872 to identify the difference observed in the SF36 MCS scores. 42 cases and 27 controls are required to give the CIQ a power of 0.8 to detect the observed difference ($\alpha=0.05$). 81 patients and 6 controls are required to give the FIM a power of 0.8 to detect the observed difference ($\alpha=0.05$).

Although there are well-recognised limitations to the use of these figures, the post-study calculations suggest that our original targets would have been reasonable and would have led to useful results for all aspects of the study.

6.4: Ethical approval

6.4.1: MREC

Ethical approval was obtained from the Multicentre Research Ethics Committee (MREC) after protracted discussions which delayed the project and ultimately limited its usefulness. MREC approval was necessary as the approval of five ethics committees were required due to the organisation of Glasgow's health services at the start of the study. The five ethics committees were:

- Southern General Hospital
- Western Infirmary
- Glasgow Royal Infirmary
- Victoria Infirmary
- Greater Glasgow Primary Care Trust.

When the study was originally proposed (2002) in substantially the same form as it was eventually performed, ethical approval was sought and gained without any queries or questions from the Southern General Hospital NHS Trust Research Ethics Committee.

The proposal was submitted to Thames Valley MREC at Berkshire Primary Care Trust in February 2003 via the COREC central protocol submission system. MREC raised concerns about sample sizes (which were difficult to predict due to the original nature of this work in the UK – this had been discussed with CSO as previously discussed); concerns that the power of the study would be low; concerns that GPs were being asked to “select” control patients (they felt this could introduce bias, but they did not suggest a viable

alternative method); and concerns that the researcher was performing assessments of both the cases and the controls and that this may also introduce bias. It was pointed out to MREC that given the existence and restrictions of the Data Protection Act, it was not possible to approach patients in any other way.

MREC also requested that the study have an "explicit opt-in" design and clarified indemnity and chaperone arrangements. The sample size was reduced to 20 cases and 20 controls to "assess feasibility" in line with MREC's request.

Changes were made to the study documentation and indemnity details were clarified. All the final study documentation is available in Appendices 1-19. A home visiting protocol was produced and chaperones were arranged at MREC's request. Discussions with CSO confirmed the author's view that chaperones were probably unnecessary but they were utilised to comply with the ethics committees' recommendations.

Business cards were produced and given to all participants with the contact details of the principal researcher and for GP information. It was agreed that patients and GPs would be approached only once; lack of response was to be taken as a refusal to participate and no further approaches were permitted.

MREC approval was obtained on 31 July 2003.

6.4.2: LREC

Following MREC approval, LREC approval for the Southern General Hospital, Victoria Infirmary and Greater Glasgow Primary Care Trust was gained and the project began in November 2003. Approval from the Western Infirmary and Glasgow Royal Infirmary followed shortly thereafter. No further ethical or logistic issues were raised by any of these five committees.

6.5: Consent

Written consent was obtained from all participants in the project. Firstly, consent was sought from the Consultants in Accident & Emergency Medicine in the four hospitals from which we sought patients for permission to study their patients. This consent was received from all without delay. As explained above, once patient and GP details were available after the STAG data were deanonymised and current addresses confirmed, any patients who were known to be deceased in the interim period were noted and removed from the patient list.

An initial letter was sent to the potential patient's GP stating the nature of the study and seeking consent from them to approach their patient. If consent for this was given, a letter of introduction was sent to the patient via their GP seeking their consent to participate. Only those who agreed in writing to take part were approached again. Any person (GP or patient) who failed to provide a response were assumed to have declined to participate and were not approached again.

Some GPs kindly nominated control patients from their own lists. Similar letters were constructed for them and they were again sent via their GP as a means of introduction to the study. Written consent was sought from them to participate in the study.

When the participants were approached for their interview and examination, they were again reminded by the author of the option to not continue. All participants were aware of the option of leaving the study at any time without their medical care being affected in any way.

All participants who completed the study verbally confirmed their willingness to participate prior to interview.

6.6: Data collection

6.6.1: Injury severity data

Injury severity data was obtained from the STAG database directly. These data consisted of:

- STAG unique identifier
- Age
- Sex
- Hospital where emergency treatment occurred
- Injury severity score
- Probability of survival
- Abbreviated injury scores for body regions
- Revised trauma score
- Nature of first operation
- Length of stay
- Number of days in intensive care
- Date of injury
- Mechanism of injury
- Mode of arrival (ambulance, self, etc.)
- Triage status (whether admitted to the resuscitation room or not).

These data were used as the basis for identifying potential patients for inclusion in the study.

6.6.2: AMA impairment scale data

AMA impairment data was obtained according to standard methods as described in the AMA Guide (Cocchiarella and Andersson 2000). Essentially, a physical examination and assessment of gait and other functions (sight, hearing etc.) was performed and the patients' current functional abilities were recorded and scored according to standard criteria. These criteria could be extremely complex and intricate, although minor differences had a negligible effect on overall impairment scores. The data collection tool is shown in Appendix 15.

The design of the study led to shortcomings in the accurate assessment of the AMA impairment score. For example, a full assessment of hearing status involves audiometry for each patient, and this was clearly not feasible for patients who were assessed many miles from hospital in their own homes.

However, although this may have introduced some systematic bias, the fact that all the examinations were performed by the same assessor means that it is likely that this will be at least consistent across all participants and should minimise inter-patient variations due to assessment.

The practical difficulties of utilising this assessment tool on patients became obvious as the study progressed and it is not easy to use in the setting that this study was performed.

6.6.3: FIM data

The author gained experience at measuring FIM scores by visiting the Rehabilitation Medicine wards of the Southern General Hospital prior to collecting data.

FIM data were collected by directly observing function as much as was feasible for the majority of the items in the tool. During a brief interview and assessment, it was not possible to directly observe some bodily functions, for example bathing and toileting; for those items, the level of function was assessed by interviewing the participant and any relative or friend that was also present. The data collection tool is shown in Appendix 16.

Patients could score a maximum of 126 (maximum score 7 x 18 items) or a minimum of 18 (minimum score 1 x 18 items). Functional levels were assessed using detailed algorithms available from the originators of the score. Individual items scores were summed to give a total value.

6.6.4: CIQ data

The Community Integration Questionnaire (CIQ) is a self completed questionnaire which has 15 items to assess the degree of integration back in to a community. It was designed as a tool for use after head injury, but it may be useful as a general measure of handicap. The CIQ is given in Appendix 17.

6.6.5: SF36 data

The SF36 health status questionnaire consists of 36 discrete questions on various aspects of health status. It can be administered face to face, by written questionnaire or by telephone, with good correlations between each mode of administration. The SF36 questionnaire is given in Appendix 18.

In this study, the questionnaire was administered in its written questionnaire format, but when the author visited each patient to assess the impairment score and the FIM, completion of the questionnaire was checked and items of uncertainty were clarified verbally to maximise completion rates for the questionnaire. The questionnaire yields data on a variety of domains of health status, which is further explained in section 6.7.2 below.

6.6.6: Work status data

A simple questionnaire was designed to obtain information on work status (pre-injury and present) and to gather information on any state financial benefits being received. Postcode data was also sought here to allow the identification of deprivation categories (DEPCATs) using the Carstairs criteria (McLoone 2004). DEPCATs are a method of categorising small subsets of the Scottish population using postcode data. They are based on the prevalence of four measures of relative deprivation in Scotland, which have remained more or less constant between 1981 when they were first described and the 2001 version which is used here.

The four measures include the proportion of households with no car ownership, male unemployment, overcrowding and social class IV and V (the lowest). Each postcode sector contains between 70 and 20 000 persons depending on location. Rural areas have smaller numbers and urban areas have higher numbers, and therefore the measure is more robust in an urban context.

DEPCAT scores have been the most popular and widely used measure of deprivation for health care purposes in Scotland for more than 20 years. The work status questionnaire is reproduced in Appendix 19.

6.7: Questionnaire analyses

6.7.1: CIQ questionnaire

Published algorithms were used to calculate CIQ scores from the raw data. Essentially, each response was given a score of 0, 1 or 2, and the total score was calculated for the entire questionnaire. However, some of the responses and scoring of individual questions varied depending on previous answers.

6.7.2: SF36 questionnaire

Published algorithms were used to calculate SF36 summary scores. The complex algorithms for SF36 analysis are given in Appendices 20 and 21. These were entered on to an Excel database and then the raw data were entered on to the database.

The resultant summary scores and domains scores were checked for accuracy by randomly selecting a number of patient's data and manually calculating the results. The consistent data check results confirmed that the formulae in the database were accurate and functioning as expected.

Two summary scores, the Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score are generated, along with eight domain scores, namely:

- General health
- Role – physical
- Role – emotional
- Vitality
- Physical functioning
- Mental health
- Bodily pain
- Social functioning

These can then all be compared to published 'norms' for different populations. For comparison, US and UK norms were used for this study.

6.7.3: Work status questionnaire

DEPCAT scores (deciles) were identified using published sources (McLoone 2004) using 2001 UK population census data and participants' home postcodes. Both DEPCAT scores were recorded if the patient was living at a different

location now compared with the time of sustaining injury. Where these differed, the lowest DEPCAT score was used for any comparisons with the other group. Current work status data was also recorded as unemployed, working or retired, along with the job title of each participant.

6.8: Statistical analyses

Normal continuous data were analysed using one and two sample t tests (SF36 summary scores, FIM, CIQ). Categorical data were compared using the chi square test (response data, etc.). Non-Normal continuous data (Ps, age, etc.) were compared using the Mann Whitney U test.

Means and medians and corresponding 95% confidence intervals (CIs) were given as appropriate. Statistical analysis was performed using SPSS v12.0. Statistical significance was set at $p < 0.05$.

6.9: Data protection issues

All written data collection instruments (questionnaires, examination sheets, etc.) have been identified only by their unique study identifier which only the author has access to. Data has been kept confidentially secure in case further secondary analyses become possible using the same dataset.

All written data were entered on to an Excel database on a personal computer. The data were transferred to SPSS v12.0 and analysed.

7: Results

7.1: General results

7.1.1: Responses from General Practitioners

We identified 223 patients through STAG who fulfilled the entry criteria for the study. We wrote to those patients' General Practitioners (GPs) asking for permission to approach them whenever those details were known. Results are shown in Table A7.1.

Table A7.1.1: GP responses

	Frequency	Percent
Yes	59	26.5
No, medical reason	14	6.3
Not registered at practice	38	17.0
Moved away	3	1.3
Unknown GP details	18	8.1
Deceased	14	6.3
No response from GP	77	34.5
Total	223	100.0

7.1.2: Responses from trauma patients

Of 59 patients whose GP gave permission to approach them, 21 agreed to take part in the study. 19 of these 21 patients were interviewed and examined and completed the study protocol - 8.5% of the total group.

7.1.3: Responses from control patients

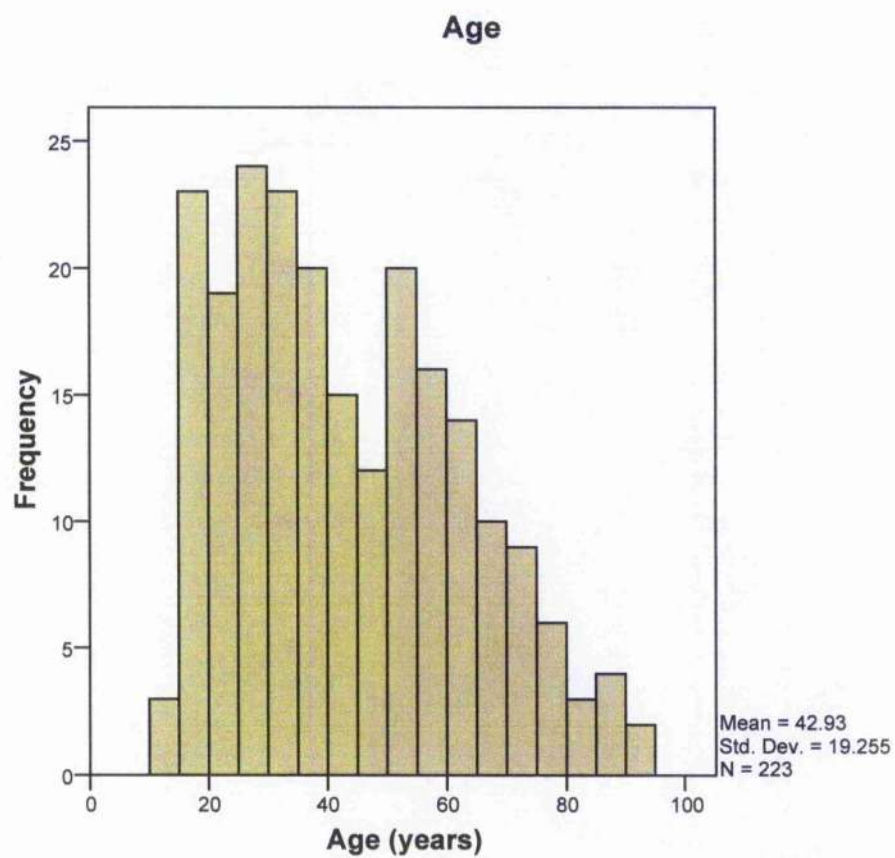
39 potential controls were nominated by the GPs of 21 patients. Several other GPs indicated that they would not nominate controls and a few indicated that they had ethical concerns with control nomination. The 39 nominated controls were invited to participate and 8 controls agreed. Seven controls were interviewed and assessed as per protocol. One was not assessed as their response arrived after study completion.

7.2: Injury severity data for study population

Median ISS for the whole group was 19 (range 16-66); median probability of survival was 0.97 (range 0.23-0.99) and median age was 39 years (range 13-92 years). The age distribution is shown graphically in Figure A7.2.1. This shows a predominantly young to middle aged population.

Figure A7.2.1

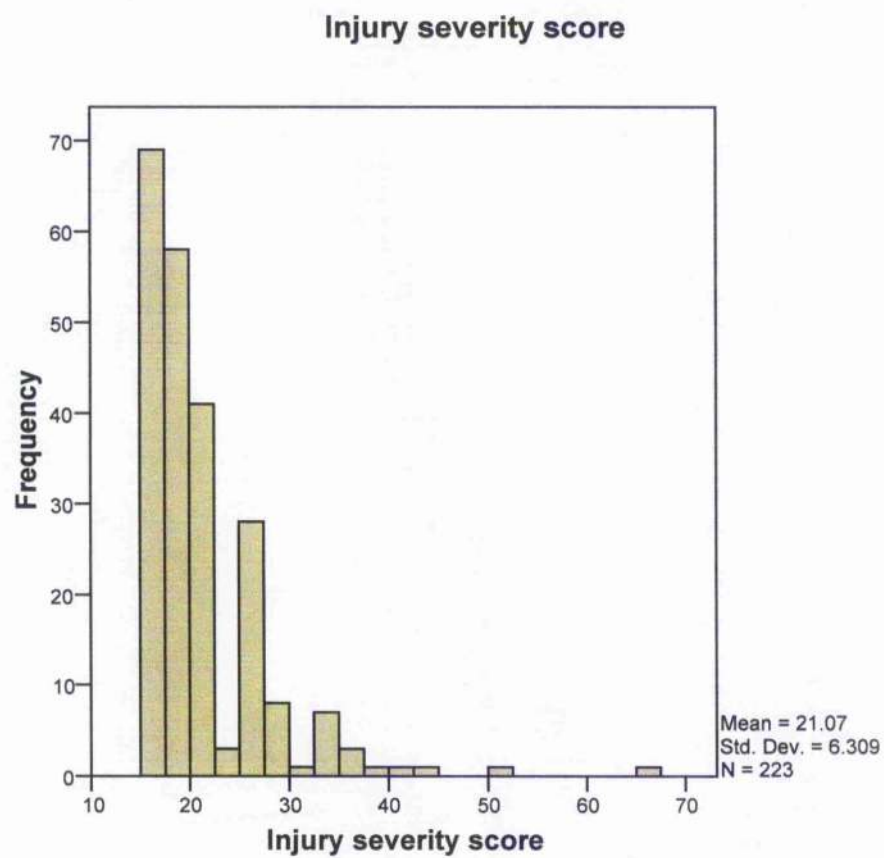
Distribution of age in whole group



The range of injury severity scores for the entire group is shown in Figure A7.2.2.

Figure A7.2.2

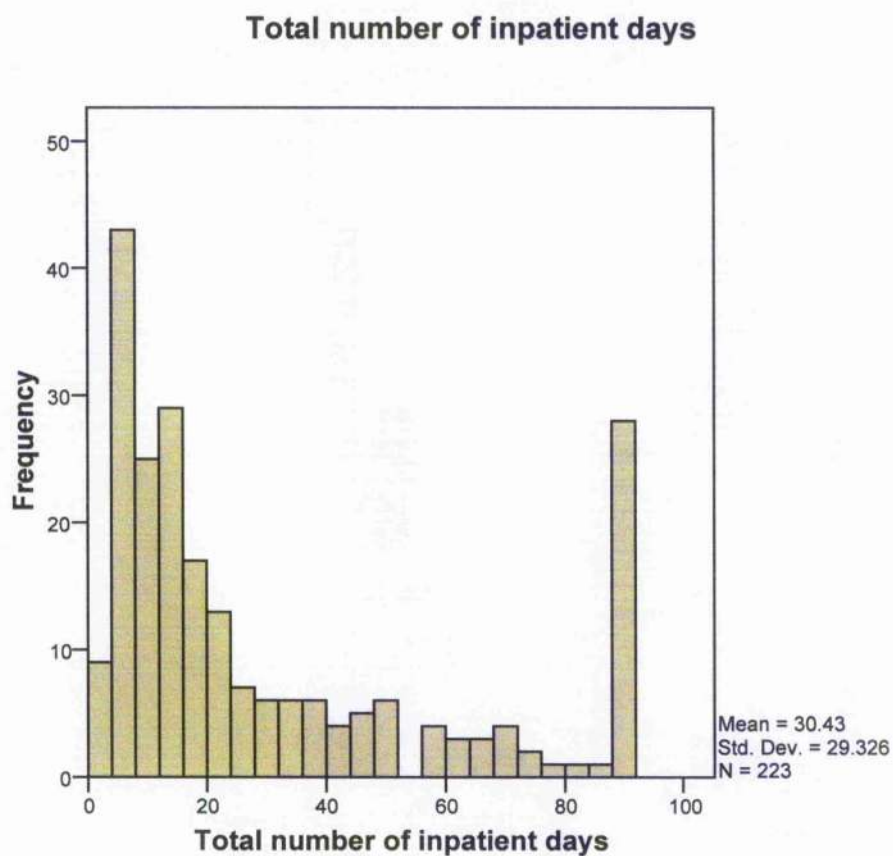
Distribution of injury severity scores for whole group



The total length of stay in inpatient days is shown in Figure A7.2.3. The second peak at the 92 day point is because that is the maximum length of follow up undertaken by STAG staff as part of the national audit.

Figure A7.2.3

Total number of inpatient days



7.3: Injury severity data for trauma cases

There were no statistically significant differences between the group who completed the study and those who did not in terms of:

- age (Figure A7.3.1)
- ISS (Figure A7.3.2)
- RTS (Figure A7.3.3)
- Ps (Figure A7.3.4) or
- total inpatient stay (Figure A7.3.5).

The only statistically significant difference was in ICU length of stay ($p=0.035$, Mann Whitney U test) but the median ICU stay for both groups was zero days (Figure A7.3.6).

In the following figures demonstrating raw data, boxplots are given which show the median as a solid black line in the centre of the box. The box represents the interquartile range (IQR), with the upper extreme at the 75th centile and the lower extreme at the 25th centile. The whiskers extend to the highest and lowest values that are within the range of 1.5 times the IQR. Outliers are denoted by circles, which occur between 1.5 and 3 times the IQR. Extremes are shown by an 'x' and denote those cases with values more than 3 times the IQR.

Figure A7.3.1

Age distribution for those who completed the study and those who did not

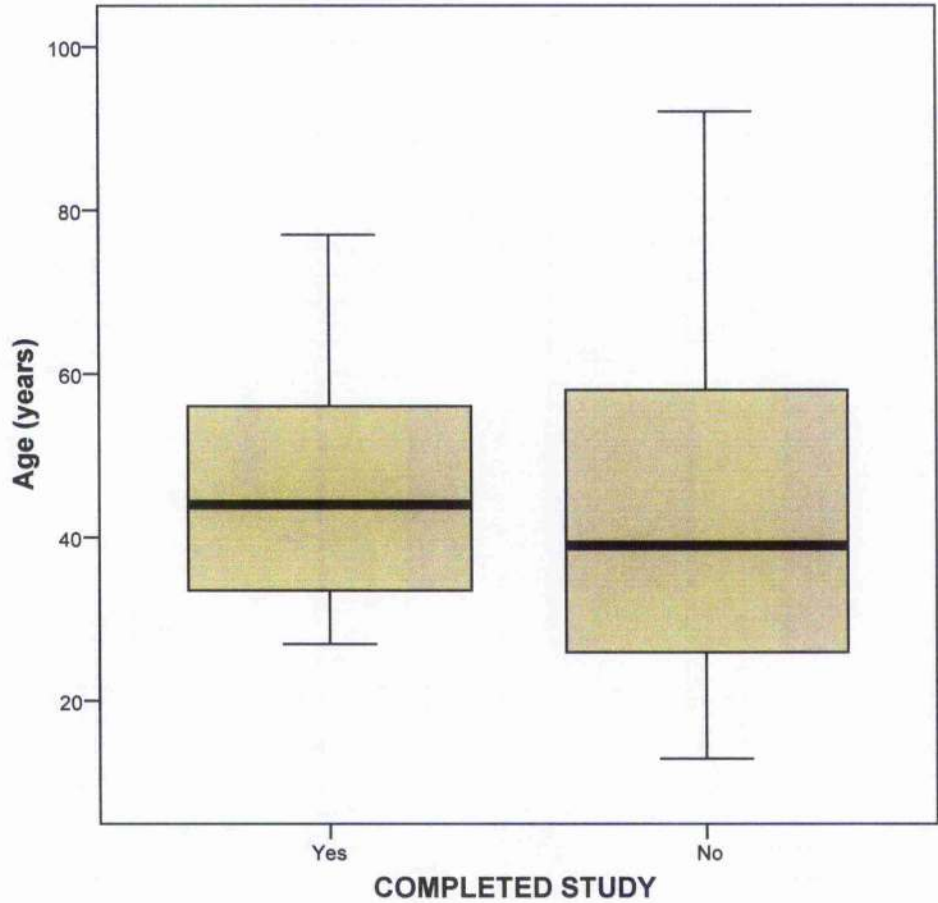


Figure A7.3.2

ISS distribution for those who completed the study and those who did not

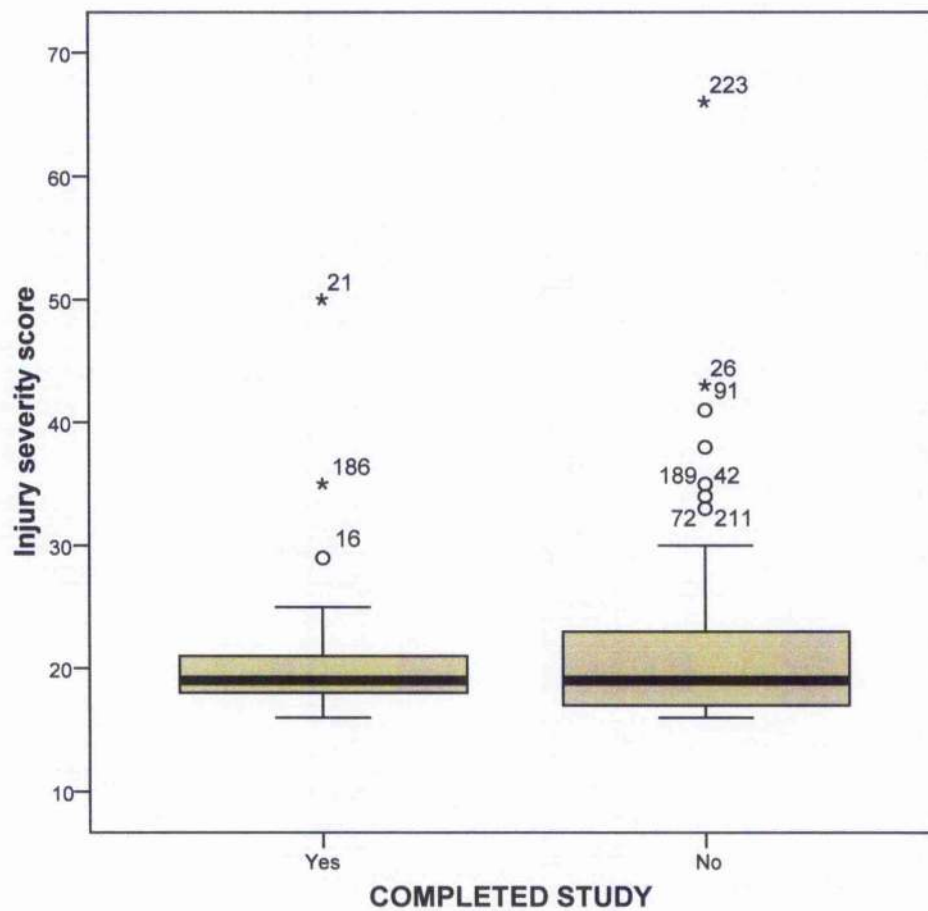


Figure A7.3.3

RTS distribution for those who completed the study and those who did not

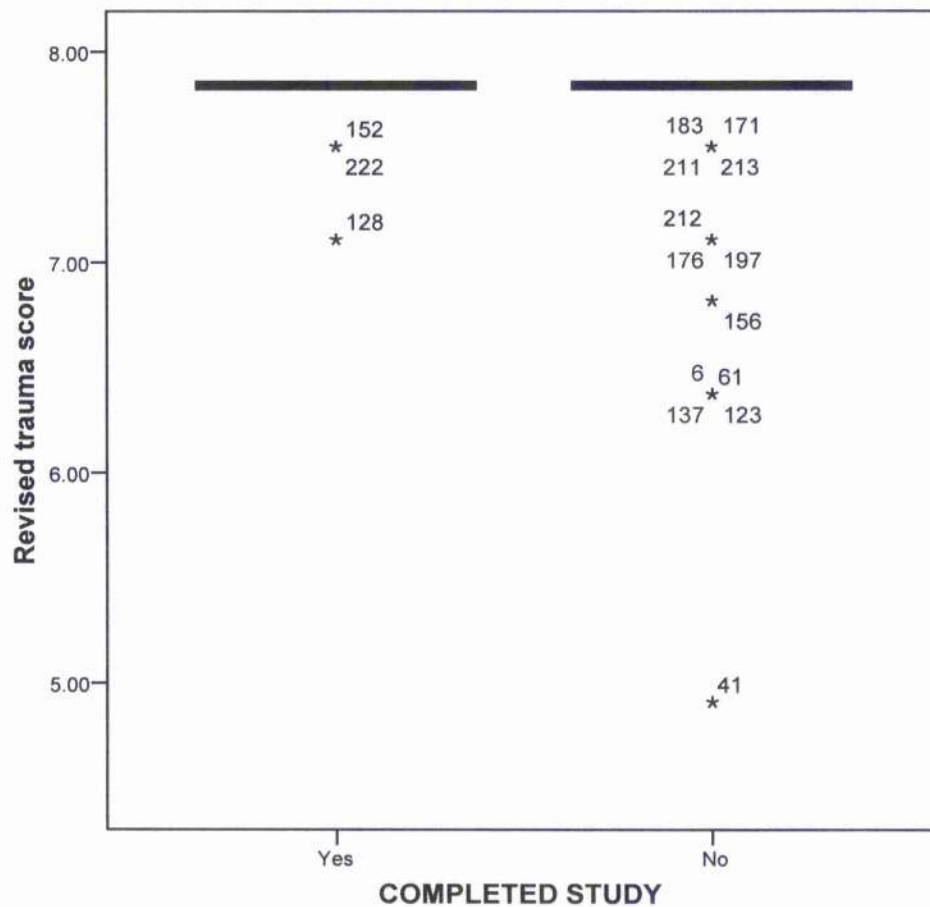


Figure A7.3.4

Probability of survival distribution for those who completed the study and those who did not

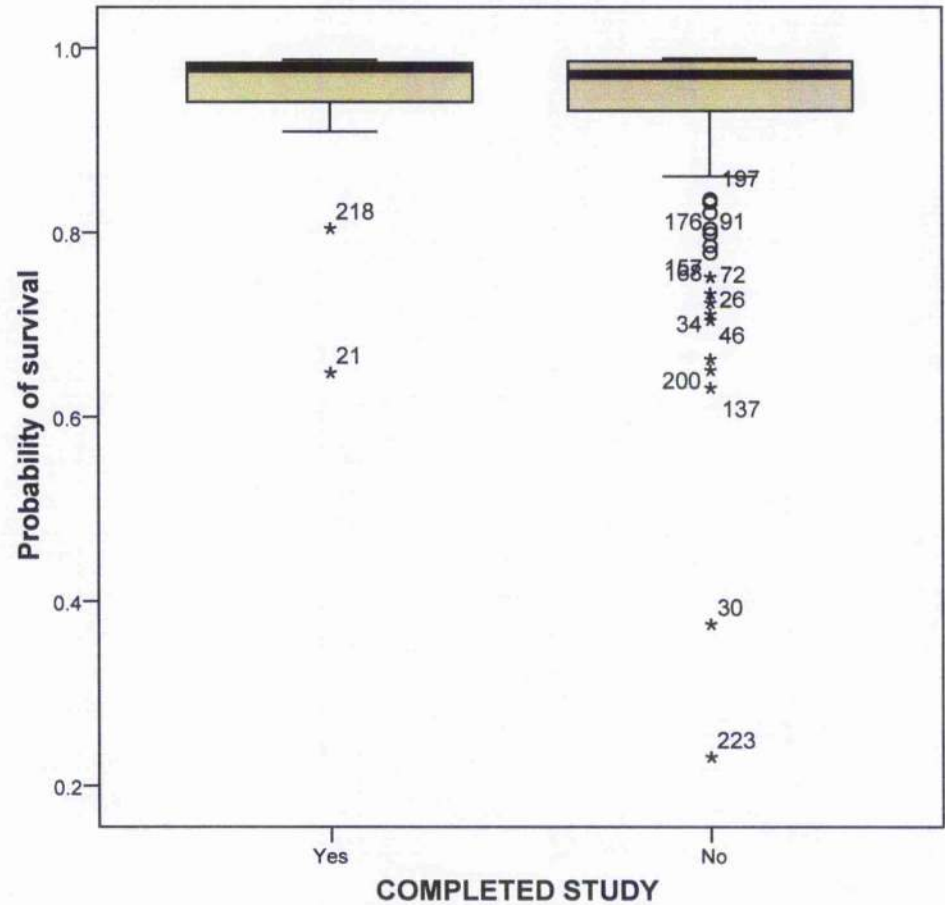
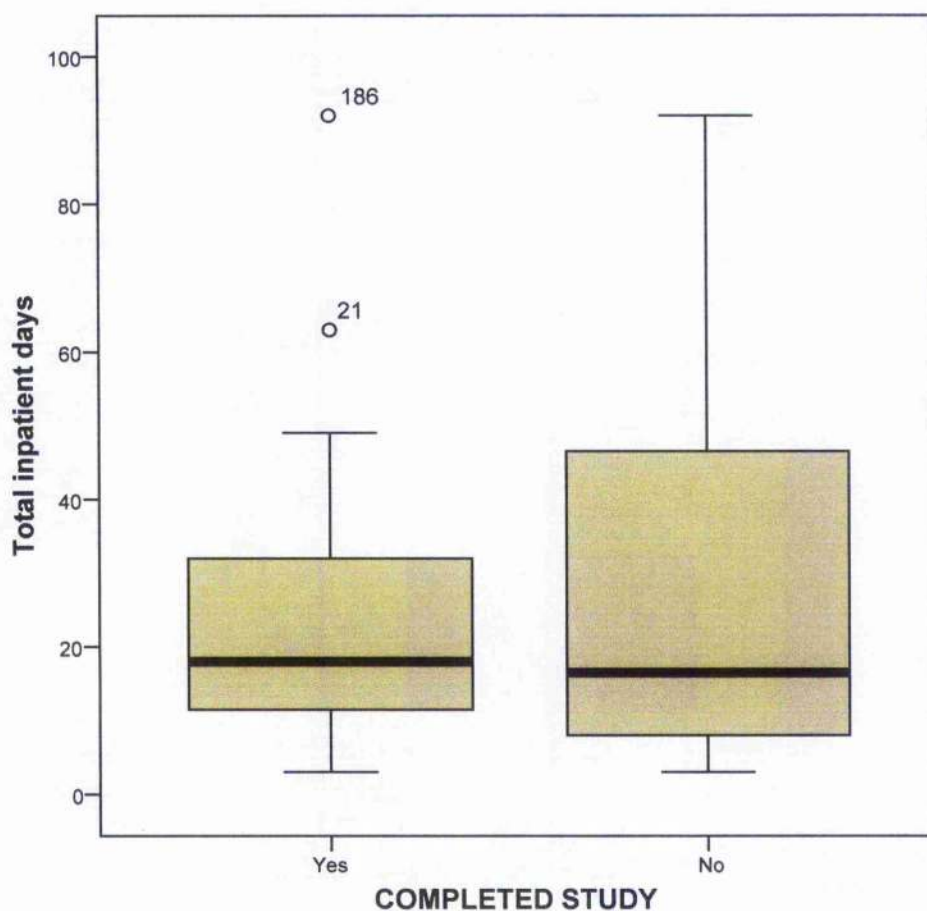


Figure A7.3.5

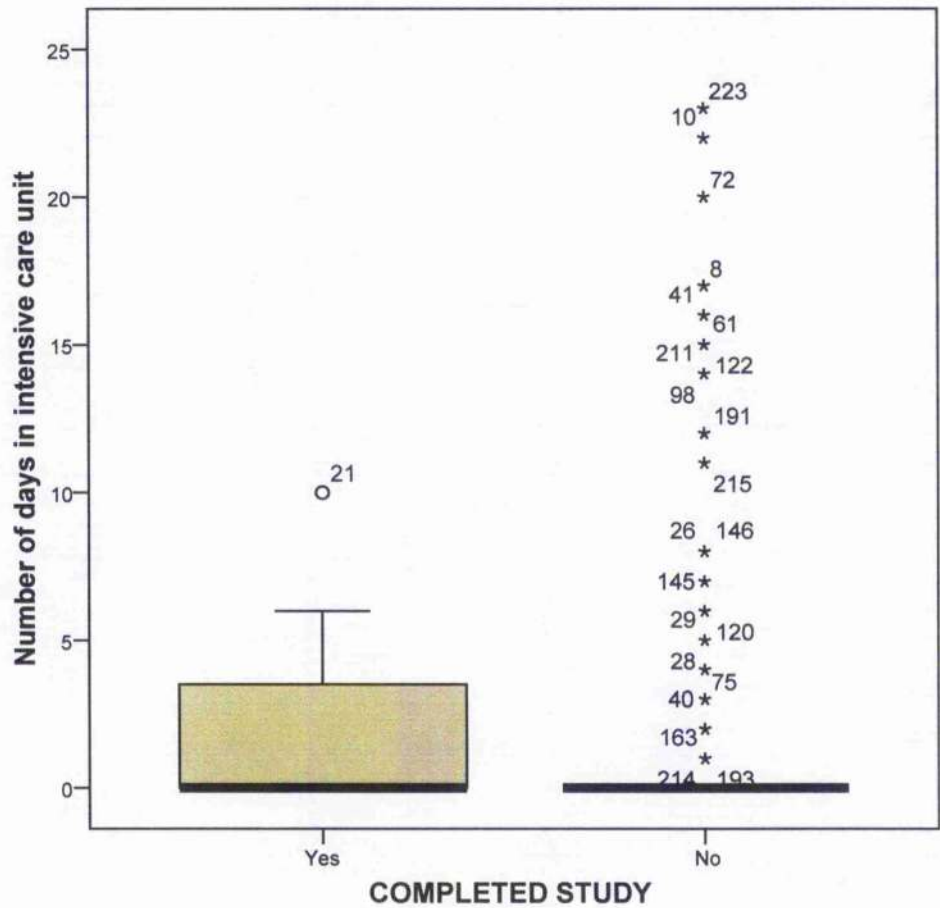
Distribution of total inpatient length of stay for those who completed the study and those who did not



Patients were followed up to a maximum length of stay of 92 days as an inpatient (by the Scottish Trauma Audit Group).

Figure A7.3.6

Distribution of length of intensive care unit stay for those who completed the study and those who did not



$p=0.035$, Mann Whitney U test

Mean length of ICU stay for those completing was 1.95 days (95%CI 0.58 to 3.32 days) compared to a mean of 1.47 days for those not completing the study (95%CI 0.92 to 2.01 days). Median length of ICU stay was zero for both groups.

7.4: AMA impairment scale results

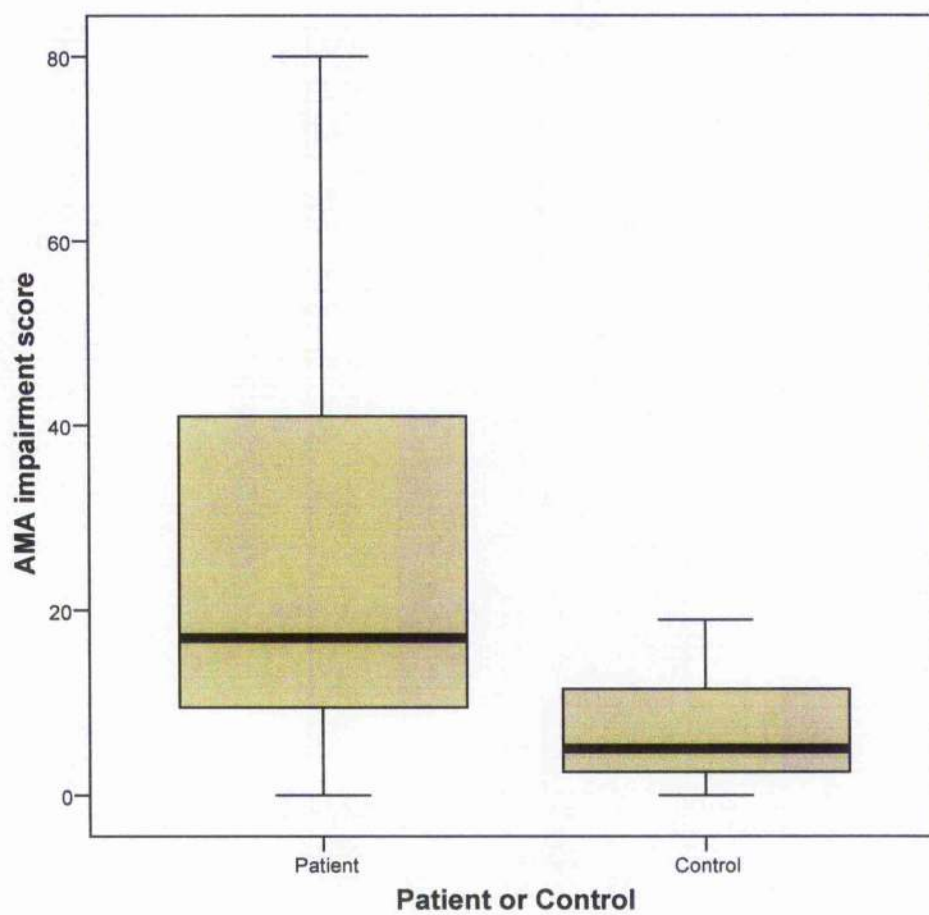
Impairment scores were calculated using the published algorithms. The median impairment score for patients was 25.9% (95% CI 14.8 to 37.0) and for control patients was 7.4% (95% CI 1.0 to 13.9) ($p=0.043$, Mann Whitney U test).

Patients have therefore significantly more impairment compared to controls.

Figure A7.4.1 shows a boxplot of the results graphically.

Figure A7.4.1

AMA impairment scores for patients and controls



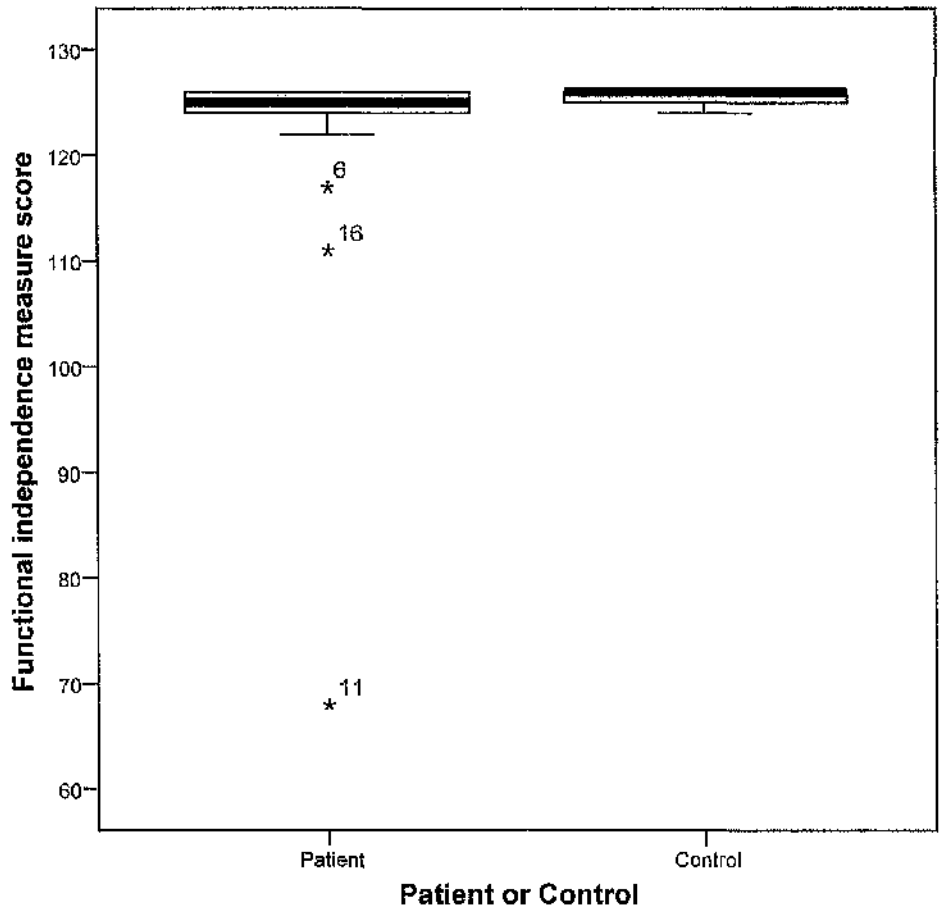
7.5: FIM results

FIM results were calculated using standard techniques. The mean FIM score for patients was 121.0 (95% CI 114.6 to 127.4) and for control patients was 125.4 (95% CI 124.5 to 126.3) ($p=0.169$, independent samples t-test (unequal variances); 95% CI for difference in means -10.9 to 2.1).

Figure A7.5.1 shows a boxplot of the results graphically.

Figure A7.5.1

FIM scores for patients and controls



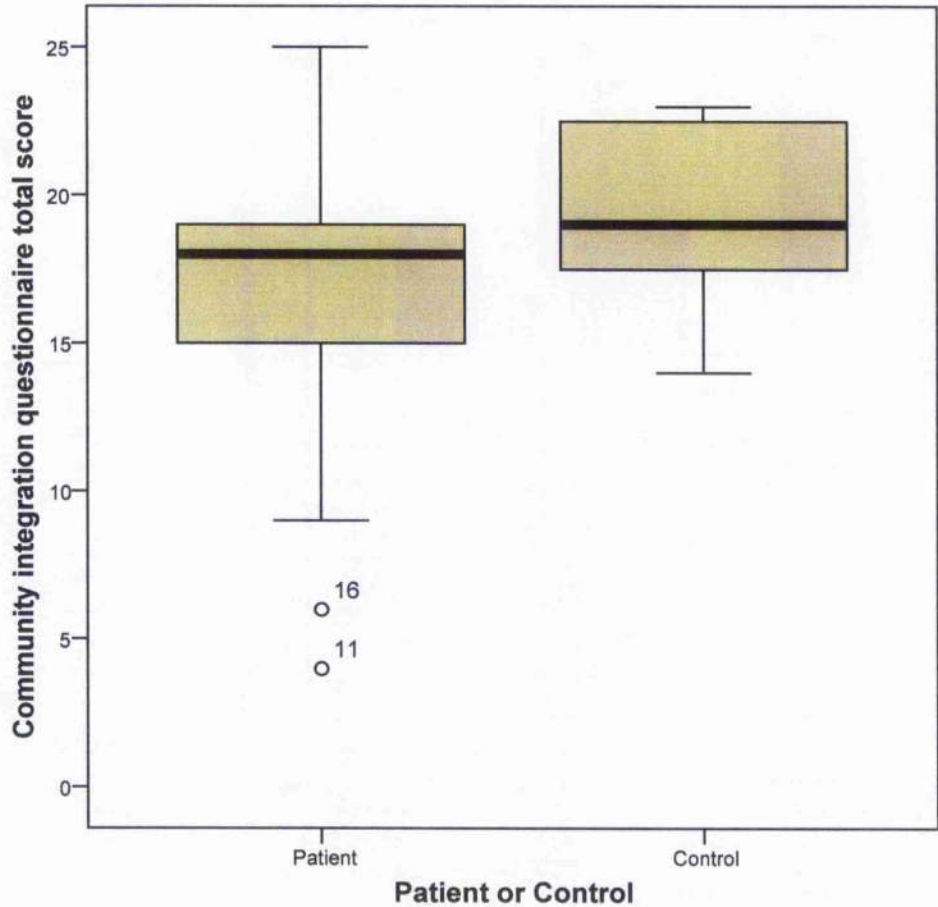
7.6: CIQ results

CIQ results were calculated using published protocols. The mean CIQ score for patients was 16.4 (95% CI 13.7 to 19.0) and for control patients was 19.4 (95% CI 16.3 to 22.6) ($p=0.106$, independent samples t-test (unequal variances); 95% CI for difference in means -6.84 to 0.72).

Figure A7.6.1 shows a boxplot of the results graphically.

Figure A7.6.1

CIQ scores for patients and controls



7.7: SF36 results

SF36 results were calculated using published protocols yielding a mental component summary score (MCS) and a physical component summary score (PCS).

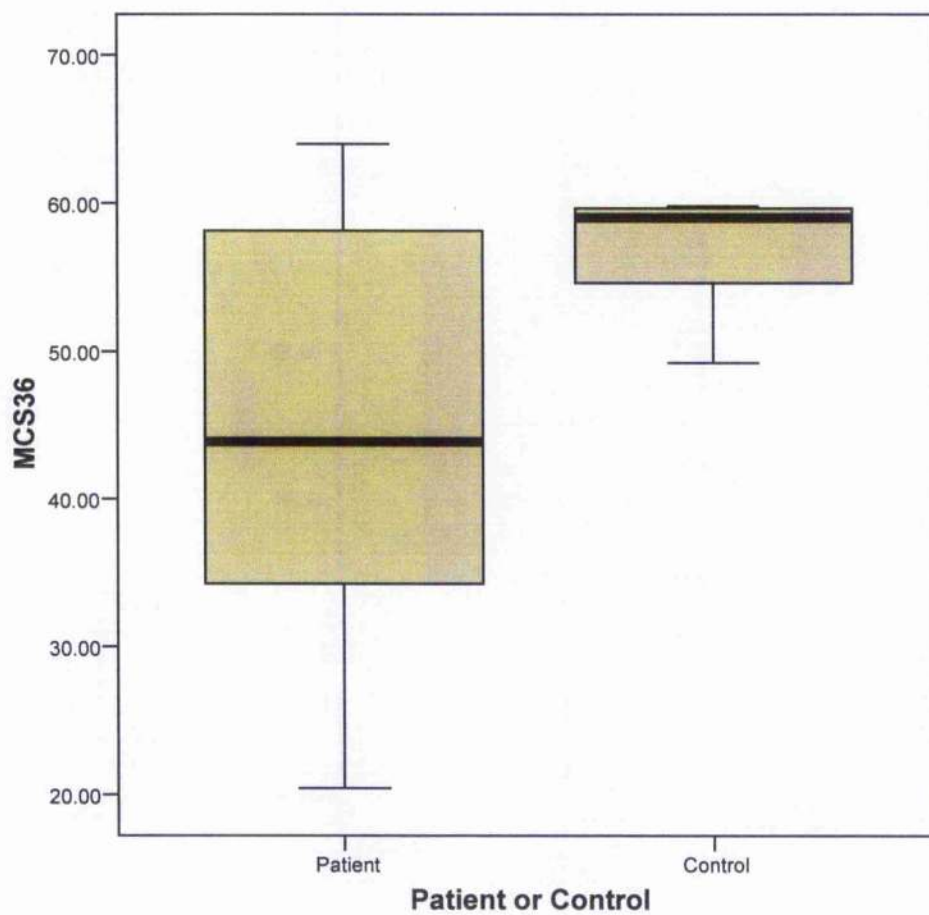
7.7.1: MCS

The mean SF36 MCS score for patients was 45.07 (95% CI 38.46 to 51.68) and for control patients was 56.65 (95% CI 52.43 to 60.86) ($p=0.004$, independent samples t-test (unequal variances); 95% CI for difference in means -18.98 to -4.17).

Patients therefore have significantly lower MCS scores compared to controls in this sample. Figure A7.7.1 shows a boxplot of the results graphically.

Figure A7.7.1

Mean MCS36 scores for patients and controls



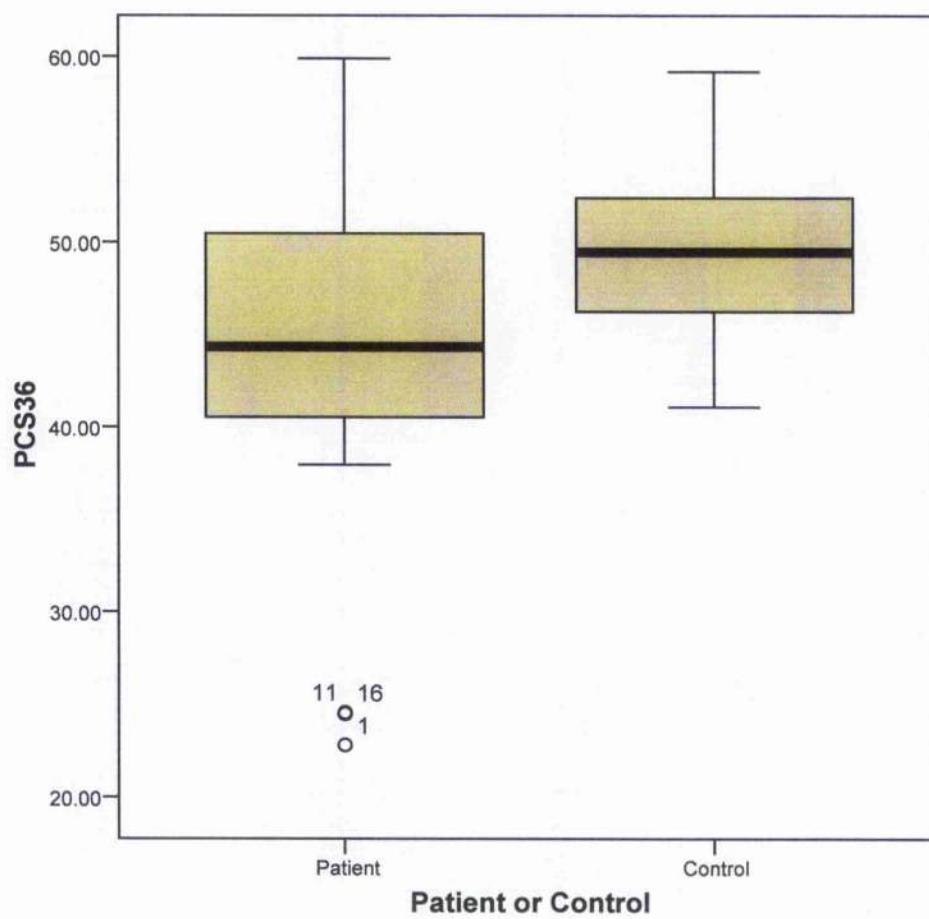
7.7.2: PCS

The mean SF36 PCS score for patients was 43.53 (95% CI 38.40 to 48.66) and for control patients was 49.56 (95% CI 44.14 to 54.99) ($p=0.082$, independent samples t-test (unequal variances); 95% CI for difference in means -12.92 to 0.85).

Figure A7.7.2 shows a boxplot of the results graphically.

Figure A7.7.2

Mean PCS36 scores for patients and controls



7.7.3: MCS and PCS compared to population normal scores

The MCS and PCS are "norm based". This means they can be compared to published population "norms". The results are shown in Table A7.7.3.

Table A7.7.3: MCS and PCS compared to populations norms

Summary Score	Mean SF36 score (95% CI)	Range	US mean	p	UK mean	p
Mental Component Summary Patients	45.07 (38.46-51.68)	20.44- 63.96	50.0	0.135	52.2	0.036
Mental Component Summary Controls	56.65 (52.43-60.86)	49.23- 59.79	50.0	0.008	52.2	0.042
Physical Component Summary Patients	43.53 (38.40-48.66)	22.82- 59.89	50.8	0.008	50.8	0.008
Physical Component Summary Controls	49.56 (44.14-54.99)	41.09- 59.18	50.8	0.597	50.8	0.597

7.8: Work status and deprivation

7.8.1: Employment and benefits status

Of 19 survivors, 13 were in gainful employment, 4 had retired and 2 were not working. Of 7 controls, 3 were employed and 4 were retirees. 6 of the 19 patients were in receipt of state benefits following their injuries, including the 2 who were not working. These included attendance allowance (n=1); disability living allowance (n=2); incapacity benefit (n=1); industrial injuries disablement benefit (n=1) and combined incapacity benefit and disability living allowance (n=1).

7.8.2: Deprivation status

Deprivation status was estimated and is shown in Table A7.8.2.

Table A7.8.2

Patient or control DEPCAT score

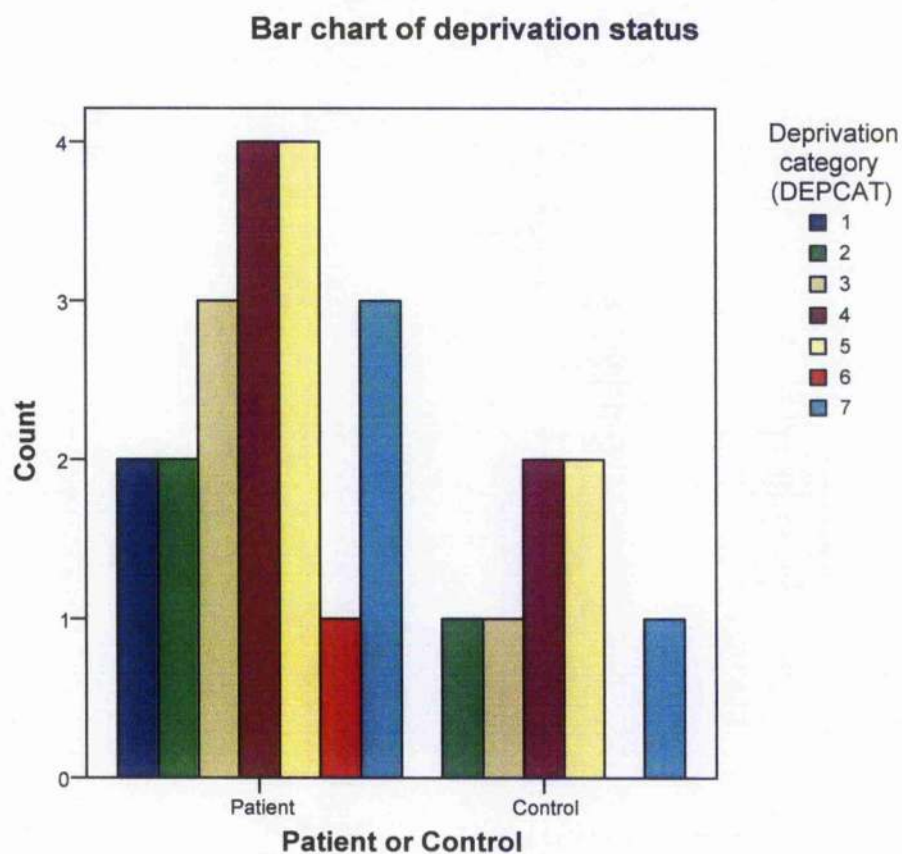
	DEPCAT score							Total
	1	2	3	4	5	6	7	
Patient	2	2	3	4	4	1	3	19
Control	0	1	1	2	2	0	1	7
Total	2	3	4	6	6	1	4	26

There was no difference between the patient group and the control group with respect to DEPCAT scores.

The distributions are shown graphically in Figure A7.8.2.

Figure A7.8.2

Bar chart of deprivation categories for patients and controls



7.8.3: Impairment score, PCS and work status

Among the survivors, there was no statistically significant differences in impairment score ($p=0.24$, independent samples t-test (unequal variances); 95% CI for difference -13.9 to 46.4) or PCS ($p=0.48$, independent samples t-test (unequal variances); 95% CI for difference -18.7 to 9.7) between those in employment and those who were not working or retired.

Figure A7.8.3.1 shows the comparison between impairment score and work status graphically, while Figure A7.8.3.2 shows the comparison between PCS and work status.

Figure A7.8.3.1

Impairment score and work status

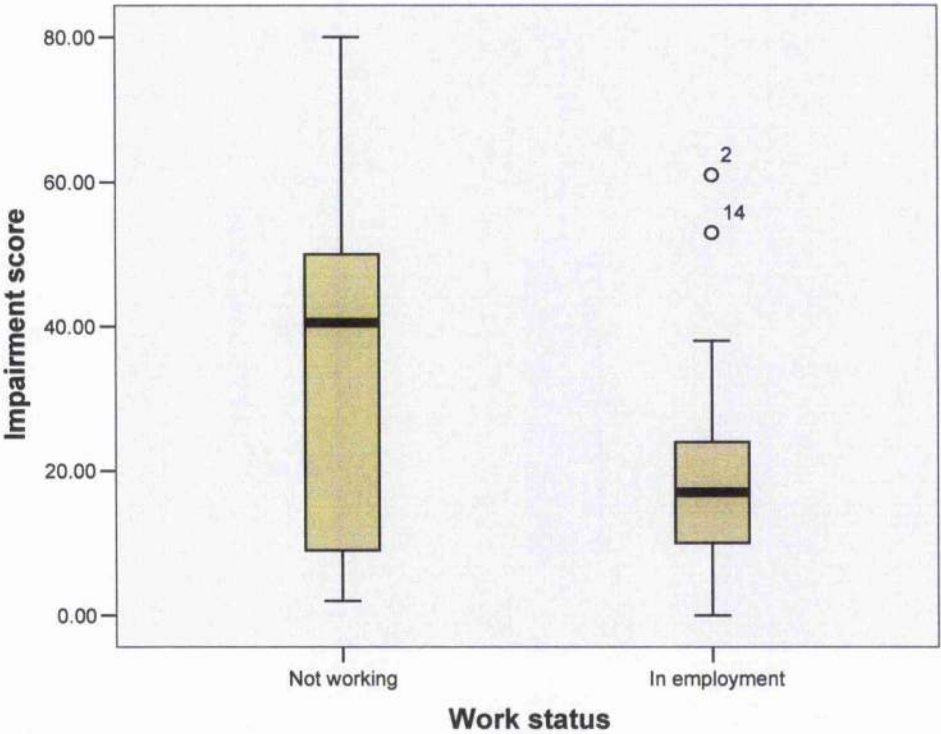
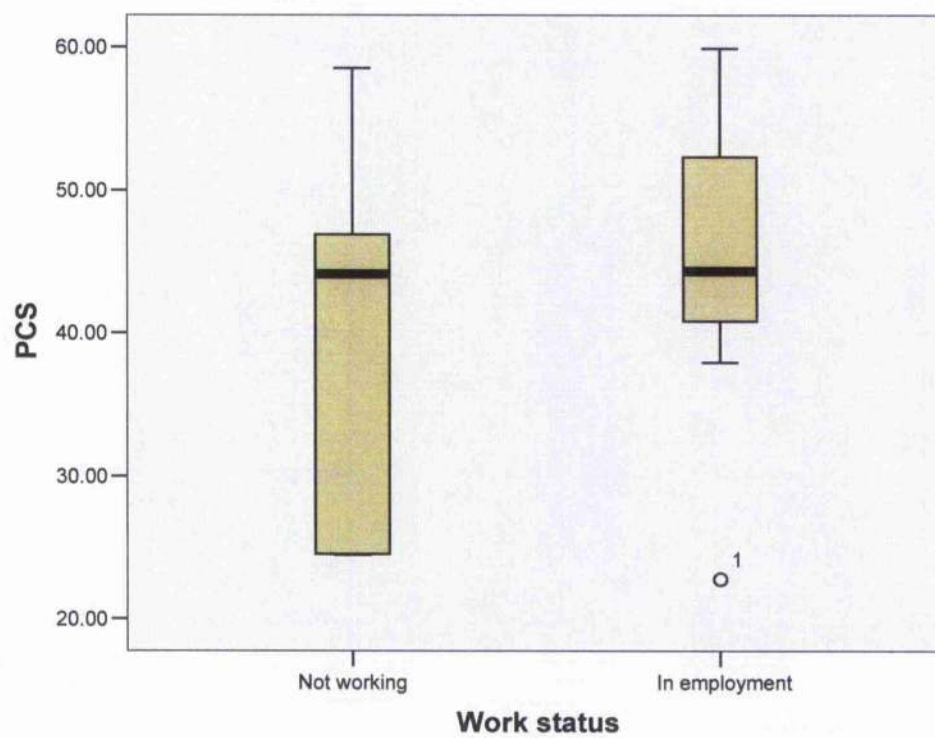


Figure 7.8.3.2

PCS and work status



7.8.4: Impairment score, PCS and state benefits

A comparison of the survivors receiving any state benefit with those not in receipt of benefits shows a significant difference in impairment scores ($p=0.013$, independent samples t-test (unequal variances); 95%CI for difference -52.8 to -8.4) showing that those in receipt of one or more state benefits are more impaired than those not receiving them.

There was a trend towards PCS scores being lower in the group receiving state benefits, but this did not reach statistical significance ($p=0.056$, independent samples t-test (unequal variances); 95%CI for difference -0.3 to 20.7).

Figure A7.8.4.1 shows the comparison between impairment score and state benefit receipt graphically, while Figure A7.8.4.2 shows the comparison between PCS and state benefit receipt.

Figure A7.8.4.1

Impairment score and state benefits

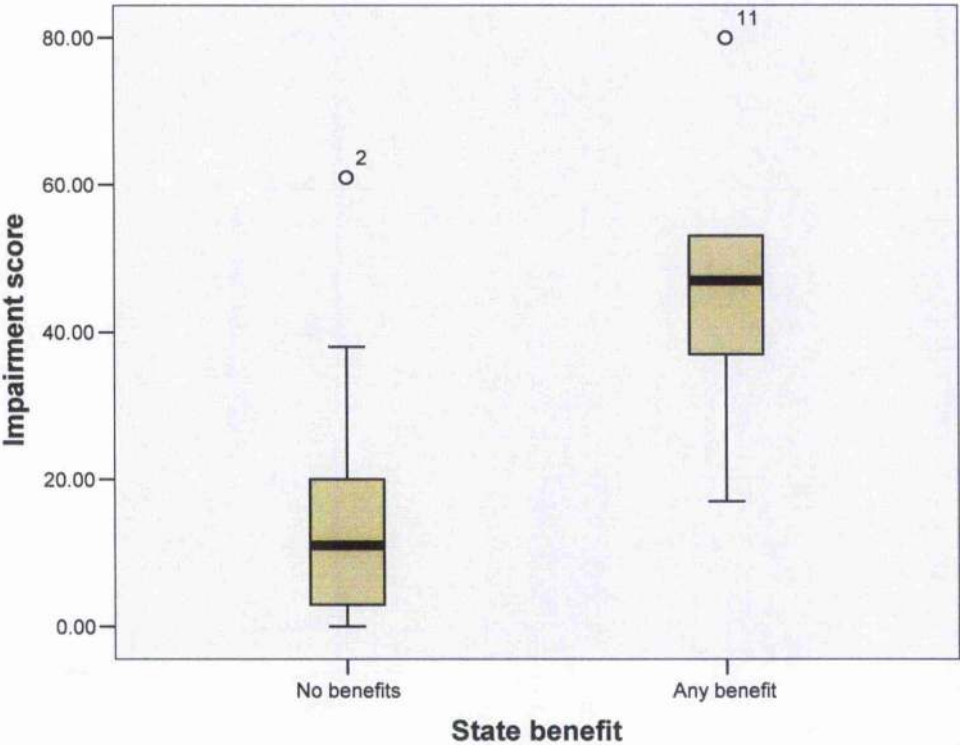
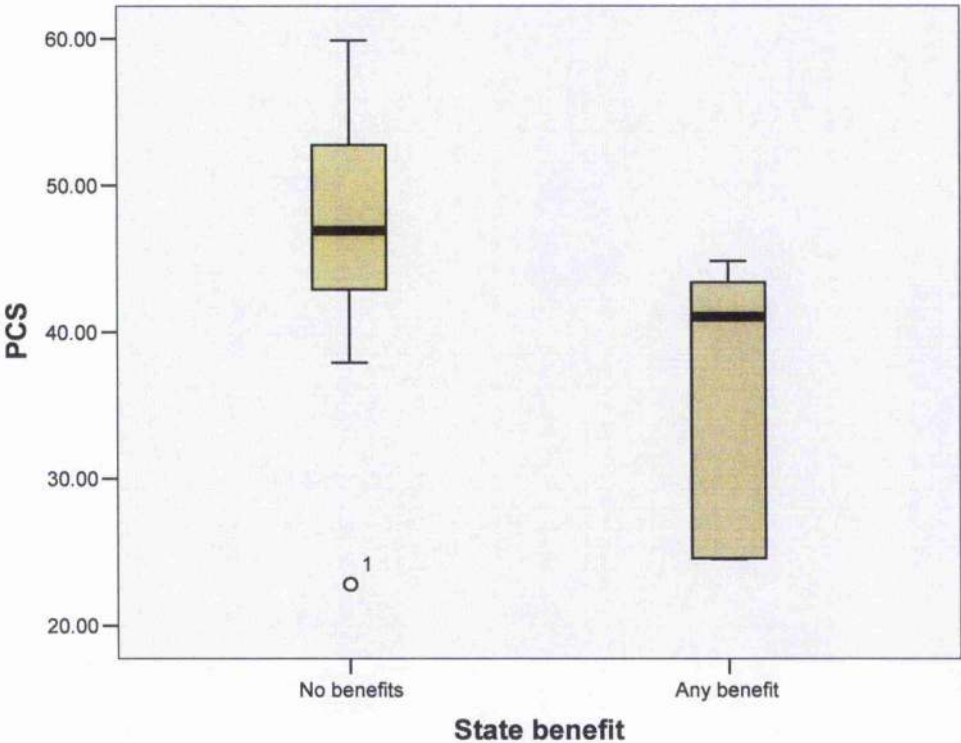


Figure A7.8.4.2

PCS and state benefits



7.9: Summary of results

19 cases and 7 controls completed the study from 223 potential cases and 39 potential controls. Participants and non participants were comparable in terms of ISS, probability of survival (Ps) and length of stay in hospital. AMA impairment score shows that survivors of trauma are more impaired than controls (25.9% v 7.4%, $p=0.043$, Mann Whitney U test).

There were no differences in FIM or CIQ scores between the groups, although a type II error is possible. SF36 Physical Component Summary (PCS) scores showed no statistical difference compared to controls although survivors' PCS scores were significantly below the UK and US means ($p=0.008$). SF36 Mental Component Summary (MCS) scores were significantly below controls (45.07 v 56.65, $p=0.004$, independent samples t-test) and UK population normal values ($p=0.036$).

There were no significant differences between survivors and controls in terms of work status and deprivation categories, although sample sizes were small.

8: Discussion

8.1: Ethical issues

The ethical requirements for this apparently straightforward and simple study posed significant difficulties for the research team and the long process of reviews considerably delayed the start of this project, which ultimately reduced its effectiveness and quality.

Firstly, the requirement to approach an MREC rather than LRECs made the process more difficult. The hospital trust system in Glasgow at the time the study was starting meant that there were three separate trusts that had a combined total of five ethics committees (LRECs) which had interests in the current study.

Although the new MREC system is designed to reduce the amount of paperwork, many authors have commented on the exact opposite in real life practice. Greenhalgh (2004) commented recently on the length of time taken to complete a new multicentre ("COREC") ethics form, complete with 57 pages and another piece of computer software to complete.

This is despite an editorial by Alberti (2000) describing the difficulties five years ago as "obstructive" as shown by two other studies (Tully et al 2000; Lux et al 2000). Crucially, they do not criticise the ethical decisions themselves, but rather criticise the workings of the system, needless bureaucracy and the lack of a standardised system.

Secondly, we were asked by MREC to reduce our sample size to one quarter ($n=20$) of our original sample size ($n=80$ per group). We had based this size on the best possible estimate, and agreed it with our funding body and supervisors.

The MREC argued that it was unethical to conduct research that would not give meaningful results (in a statistical or clinical sense) which is entirely valid as a reason to change a sample size. However, it is also reasonable to counter-argue that reasoning, and state that the requirement to undertake small scale studies that have little statistical or clinical impact is in itself unethical and should have been avoided.

If this approach was agreed, we could have either proceeded with the study, to look at the results with our best possible estimate, or we should have abandoned the study entirely. To do that would potentially deny future patients of improved treatments, and that could be argued to be unethical as well.

Practical matters also come into this dilemma. As a postgraduate specialist trainee on a fixed term research fellowship, it would of course be preferable to come to a planned project with ethical approval already in place, but in emerging fields such as emergency medicine, where such planned research programs are currently rare in the UK, this is not always possible. Obviously patient safety and ethics are the highest priority of any ethical committee, and rightly so, but the pressures of the research environment and the time pressures in particular can make medical research even more difficult for emerging specialties.

It is clearer now that if we had studied the originally planned numbers in the study, the study may have produced more meaningful results which could have further informed practice and future research.

Martyn (2003), in a provocative editorial, suggests that many members of an ethical committee are not competent to make judgements on the merits of individual projects. To illustrate, one member of the committee to which this project was submitted had only one "PubMed" listed publication in the medical literature, and none of the members of the committee came from disciplines relevant to the project (although it is of course acknowledged that they may have had relevant experience from other relevant fields).

Martyn's comments certainly echo with the experience observed in this study, experiences that can give rise to further frustrations and questions for researchers in this and other fields.

The LRECs were generally efficient, but they all suffered from the problems previously detailed by Alberti (2000) and others – different forms, different requirements, and vast amounts of paper being used to satisfy requirements. The system undoubtedly exists to protect the safety and rights of patients, but in the age of information technology, there must be more time- and paper-efficient methods of performing this task.

Kvalsvig and Unsworth (2002) reported their experience of an MREC application associated with various other ethics committees, commenting on the

lack of issues with the scientific aspects of their study but the endless changes to patient letters which at the end of the day, made little change to the study and little change to the process that patients in the study had to go through. Their final comment is worth reproducing in full:

"We wonder how many others have been discouraged from pursuing research interests after floundering in this quagmire."

(Kvalsvig and Unsworth 2002).

Once MREC and LREC approval was obtained, the study progressed without significant incident. A few general practitioners commented that they were unwilling to nominate their own patients as control subjects and cited 'ethical concerns' without further specifying them. Ethically, we did not feel able to pursue this further as we were bound by MREC to approach potential participants only once and accept any decision without further question.

A fascinating and well performed randomised controlled trial was published after the conclusion of the data collection part of this study by Junghans et al in 2005. As part of an observational study of patients with ischaemic heart disease, they randomised patients to an 'opt-in' consenting strategy and compared this to patients with an 'opt-out' approach to consent. Their study was well designed and executed, and showed that an 'opt-out' approach to consent gave rise to a 50% final response rate compared to 38% for an explicit 'opt-in' approach.

Further analysis suggests that in their population, those who 'opted-in' were less relevant to their study as they were healthier, and therefore the 'opt-out' method was more appropriate given their aim to observe patients for progression of ischaemic heart disease over time. This has major implications for studies such as the current one: such a strategy may well have improved the final response rate and reduced the selection bias that may have been present according to this study.

Any further work derived from this study would certainly try to adopt these inclusion criteria rather than submitting to an 'opt-in' system if at all possible. Further research is clearly required to see if it is possible to repeat these results in other parts of the UK (the trial was done in London) and in other countries to help clarify the true potential of such approaches.

It is difficult for the research team to accept individual idiosyncrasies of family doctors once the project has been approved by one regional and at least two local committees, including a primary health care committee, but there is no other option but to accept their decision and proceed with the study.

Given the pressures of the data protection legislation in the UK, the reluctance of GPs to divulge information to a relative stranger is understandable. However, it could be argued that the study is for a greater public health need and therefore individual doctors should be willing to support it.

We did not offer any incentives to potential participants to take part in the study, which we believed was ethically sound and in accordance with accepted

practice. However, other recent UK work (Mason et al 2002) offered completing participants in a clinical outcomes study the sum of £10 as a contribution towards their time for taking part in the experiment. This study was approved by their local ethical committee in the usual manner.

If such an approach becomes generally accepted, it may allow higher participation rates from control patients in particular, which may make this type of study easier in the future.

8.2: Characteristics of study and control group

The group we studied was the appropriate target group to answer the research questions we raised. However, the response rate was very low. The requirement to request permission from the GP to approach each patient was entirely appropriate to protect patients' wellbeing. Patients may well have changed in terms of both mental and physical status in the intervening period since they sustained their injuries.

If they had developed serious psychological or psychiatric issues then it may be appropriate not to approach these patients for a study such as this. However, this approach, while ethically appropriate, automatically introduces bias into the sampling for the study.

Trauma follow up studies will always be biased if such a sampling strategy is employed for ethical or other reasons. It may be more useful for follow up studies to recruit patients at the time of injury, and this would be a useful

strategy for future studies. Obviously, this would have significant funding implications for future studies in terms of timely recruitment and ongoing follow up costs.

Only 26.5% of patients' GPs responded positively. It is difficult to follow up a large group of patients several years or more after possible last medical contact; it is therefore not surprising that some GPs were no longer looking after their original patients.

The fact that the GPs prevented 14 deceased patients' families from receiving unwanted and unnecessary requests to participate in research shows the usefulness of approaching GPs prior to approaching patients. The only other methods would be to follow patients up from the time of admission (as mentioned above) or to check the names against the Register of Births and Deaths in Scotland.

A possible alternative method of tracking patients would be to utilise the Community Health Index (CHI), a computerised database of all patients registered within the NHS in Scotland. It is used to track medical records, and may have been useful to identify addresses of patients within Scotland if they had moved residence since their injury was sustained. We did not explore whether or not there would have been additional legal and ethical issues to access this data, given the existing difficulties that were experienced (see above, Chapter 8.1).

However, there are still risks to this approach as people can die overseas or be alive but have serious psychiatric morbidity. Therefore, the individual GP probably remains the best person to assess whether or not specific patients should be approached.

What is disappointing is the fact that over a third of GPs did not respond at all to the requests for information. Researchers appreciate that GPs probably receive many such requests every day or every week, and to answer each one is probably unrealistic.

However, participation in research is a fundamental part of medical practice, and the lack of participation in ethically approved research projects leads to low response rates which then depresses the quality of medical research generally. Financial incentives to GPs to encourage participation may be worthwhile, but they are considered ethically unacceptable by many researchers and ethics committees.

Unless the GP sees some benefit to the individual patient by participation (such as a randomised controlled trial of a new drug therapy), they are less likely to agree to the patient's participation. They are even less likely to agree to nomination of a control subject, such as in this case-control study design. It follows that a registry type follow up study, where patients agree to participate in long term follow up at the time of hospital admission or discharge, may be a better option for future studies. They will however, cost more and take longer to set up.

Once GP permission to approach had been received by the investigators, a letter was sent back to the GP for onward sending to the potential participant. This introduced another potential hurdle in terms of contacting the patient directly, as the GP could have ignored the letter or thought it was a duplicate of the previous communication. Again, this was felt to be the only ethically reasonable way to make contact with the patients in the eyes of the ethical committee.

This may have led to the low response rate for this part of the study, with 21 patients agreeing from 59 patients whose GP's had given permission to approach. After agreement to participate, the vast majority completed the study. It is clear therefore that the difficulty was gaining access to the patients in the first place. If we had been able to approach the patient directly after GP permission had been given (which was part of the original study design) then it is possible that we could have had a higher response rate. Alternatively, we may have had a lower response rate due to being approached by a relative stranger.

Alternative study designs, perhaps based on a registry concept from the time of hospitalisation, may have better response and completion rates than the approach we used.

A similar number of control patients were nominated, despite the request to the GPs to nominate two controls for every patient that they allowed us to approach. This suggests that GPs were even less willing to nominate control patients, although we have no objective data to explain why.

It is understandable that GPs may be reluctant to nominate a "normal patient" to take part in medical research, especially as there is no perceived benefit to the individual involved. The study design attempted to acknowledge that by minimising the effort that control patients had to put in, by offering to meet them for their interview at home or at hospital depending on their preference.

There was a poor response from the nominated control subjects, possibly contributed to again by the requirement to route all invitation letters via the GP. It should be stated that the researcher found all the actual participants, both patients and controls, extremely willing to help and give up their time to support the research project.

8.3: Injury severity data

The target study group was severely injured, with a median ISS of 19. They were predominantly young to middle aged, and in their prime working years. There were no statistically significant differences in age, sex, injury severity or degree of physiological compromise at presentation, or length of inpatient stay, between the target study group and the group eventually studied. The only statistically significant difference was in the number of days in ICU, but the mean length of stay differed by only 12 hours. Therefore, from a clinical perspective, the two groups' baseline characteristics were comparable.

8.4: AMA impairment data

There was a statistically significant difference in impairment score between the group of trauma survivors (mean 26%) and the control group (mean 7%), indicating that the survivors had more physical impairment than the controls.

This difference was readily apparent clinically, which suggests that the AMA impairment score is clinically sensitive to different degrees of impairment in this population. The major difficulty with the AMA score is the method of recording and analysis, as it requires a trained clinician to make detailed examination of individual patients and the guidebook recommends the use of specialised tests in many cases, some of which were used in the current study.

However, if the AMA score was calculated precisely according to the methods described by its developers, it would take many hours to generate a single impairment score for one patient, which renders it impractical for long term follow up of a significantly sized population.

Although the developers of the AMA score indicate that the score should only be estimated by a doctor, it may be interesting to identify if other health care professionals, such as nurses or physiotherapists, could be trained to estimate equivalent scores to those obtained by medical staff as this would allow the use of such professionals to follow up trauma patients in the future. It is unlikely that a system using doctors to estimate values such as the AMA score would be economically or clinically viable in long term research.

Thus, although the AMA impairment score was sensitive to the impairment of the survivors of major trauma in this study, its use in everyday routine follow up of trauma survivors is unlikely to follow.

8.5: FIM data

There was no statistically significant difference in FIM scores between the group of trauma survivors (mean 121) and the control group (mean 125). This means there was no difference in functional independence (used as a surrogate of ability [disability]) between survivors of trauma and the control group.

The lack of difference is at first surprising. However, other studies have suggested a significant ceiling effect for the FIM, which implies that it cannot detect subtle differences in functional performance at the highest (ceiling effect) or lowest end (floor effect) of the functional spectrum. The current study may be an example of the ceiling effect.

Secondly, activity is the restriction of ability, or inability, to perform the normal activities of daily living. Activity is therefore a measure of morbidity following trauma and represents the individual's response to their impairments (Hetherington and Earlam, 1994).

This definition reminds us that restriction of ability is a complex interplay between the physical limitations imposed by injury (impairment) and the individual's response to that impairment (which may arguably include society's response to that impairment in certain circumstances), such that the observable

or measurable difference between a survivor of trauma and a control was insignificant. There may still be a difference, but it is not possible to measure it with the FIM score as it is not sensitive enough.

Although the FIM was rapidly performed, it required direct observation of the patient and their activities, and training was required in order to use the score. The observed ceiling effect suggests that as a marker of long term ability in survivors of trauma, FIM is not a useful tool in this population. That is not to say it is not a useful measure: in the initial follow up of rehabilitation progress of brain injured patients in an inpatient setting, it may well be very useful, but in the context of non-head injured patients, it adds little.

8.6: CIQ data

There was no statistically significant difference in CIQ scores between the group of trauma survivors (mean 16.4) and the control group (mean 19.4). This means there was no difference in community integration (used as a surrogate of participation [handicap]) between survivors of trauma and the control group.

Although there was a trend to survivors having a lower CIQ, this did not reach statistical significance, which may be related to the small sample size and low power. The CIQ was self completed by the majority of patients and controls, and there was little reported difficulty in completion.

The CIQ data may be an example of a type II error, i.e. the study is underpowered to show a true difference when one exists. It is not possible to

comment further given the lack of a statistically significant difference, but CIQ as a marker of participation merits further study in this population in a larger study. Its ease of administration makes it an attractive tool for use in postal and other follow up studies.

8.7: SF36 data

There was a statistically significant difference in MCS score between the group of trauma survivors (mean 45) and the control group (mean 57), indicating that the survivors had poorer overall mental health status than controls.

The MCS scores for survivors were significantly lower than controls and when compared to the UK population, although not the US population. This is not entirely unexpected, and this difference was clinically apparent, but it is useful to see that the MCS score was sensitive to the observed and perceived difference. The MCS scores for controls were significantly higher than the UK and the US general population scores, which suggests the possibility of bias in those who volunteered as study controls. This supports previous comments in the selection process for controls, and confirms that the case control approach may lead to spurious differences between groups due to unconscious biased selection on the part of GPs and through self selection.

There was no statistically significant difference in PCS score between the group of trauma survivors (mean 44) and the control group (mean 50), indicating that the survivors have similar overall physical health status compared to controls.

The fact that the PCS scores in the survivors were not different to the control group reflects the small numbers in each group. This is especially so given the fact that there was a significant difference between survivors and the general UK and US populations. The results suggest the possibility of a type II error, i.e. a difference is present but the study was underpowered to demonstrate it.

There is a clear trend in the direction of survivors having a lower PCS than controls, and the AMA impairment data would also suggest that this is the likely direction for PCS (although PCS measures health status rather than physical impairment, the domains are similar in nature).

The data do show convincingly that survivors have poorer physical health status than the general populations in both the UK and the US, and this is in keeping with the AMA impairment score data for this population.

The major advantages of the SF36 questionnaire were that the instrument was self completed, and there were few queries from patients or from controls at interview on the content of the questionnaire or difficulties in SF36 completion. The SF36 has been rigorously developed and tested as a generic instrument, and has been used in many different clinical situations including trauma.

The SF36 appears to be a user friendly and readily available tool for use in assessing trauma survivors. It has the added advantage that it is suitable for repeated testing, that is to say it could be used to longitudinally monitor patients as they recover from trauma rather than just being used as a one-off measure of health status.

The principal disadvantage is that the SF36 is a registered trademark, and use of the instrument is subject to licence, as was the case in this study. The requirement for licensing costs money, although it is set at a reasonable level for academic institutions, but this has implications for ongoing research funding.

8.8: Work status data

Most survivors of major trauma returned to work or to retirement, with only two individuals not working. Only one of these two was working at the time of injury. This suggests that non head injured survivors of major trauma have a useful employment outcome if they survive initial hospital treatment. Deprivation category of home residence at the time of injury did not significantly differ between controls and survivors.

8.9: Correlations between work status, benefits and scoring systems

There was no difference in impairment score or PCS between those in employment and those not in employment or retired, suggesting that physical impairment or physical aspects of health status are not the major determinants of returning to work.

There was a significant difference in impairment scores between those receiving state benefits and those who did not, indicating that only the more severely impaired receive benefits. There was a non-significant trend for PCS to mirror the findings seen with the impairment score, but this again is likely to be

an example of a type II error due to low numbers. If the SF36 PCS could accurately identify those with a high chance of having a low impairment score, this could have implications for the identification of trauma survivors who might be eligible for benefit support on hospital discharge.

8.10: Limitations of study

The most problematic limitation of the study was the lack of numbers of patients and controls. This small study shows very well the practical difficulties of measuring long term outcomes from trauma in Scotland. The undoubted ethical difficulties that this study faced did not assist in its execution, and hopefully ethical issues will be at least administratively easier as ethical committees further mature.

How could we have improved the study? We should have done a rigorous pilot study to identify potential difficulties, as there was a lack of literature to support any design or approach. However, to identify all the difficulties we have now discovered would have taken as long as the study itself. What this study can do is inform future research in the field so that the same mistakes are not made again.

In any future study, a registry based approach may work better, i.e. patients are identified during their admission and permission is sought for them to be followed up on a regular basis up to and following discharge to evaluate serial progress. Such a cohort study would address many of the ethical issues that

this work had difficulties with, and a control arm could also be built in to such a design.

The instruments used for any future study would also have to be carefully selected. The AMA impairment score is too cumbersome for routine use, and the FIM suffers from significant ceiling effects. The SF36 is sensitive and easy to use, but requires annual licensing. The major advantage of the SF36 is that there are well validated UK and US normal values, which allows comparisons across populations and with selected diseases. The CIQ warrants further large scale study, and is ideally suited to repeated longitudinal surveys. Work status is also a useful and easily measured marker and is of huge economic and societal significance, and this should also be included.

Such a design would allow trauma follow up to be done by non-medical research staff which would reduce costs and possibly improve quality of data collection. Of course, this would only apply to patients with non significant head trauma, as this was the group studied here, and it may not be comparable to patients with significant head injury. A cohort design would allow a serial comparison of such an approach to be made.

8.11: Possible future directions

Further research could evaluate the effect of improved mental health support and services on the long term recovery of major trauma survivors, for example the effect of psychiatric support to patients after discharge from the acute hospital. The SF36 (by postal questionnaire) could be used to evaluate long

term outcomes of survivors of specific groups of trauma patients, for example orthopaedic trauma patients or non head injured survivors of major trauma in other areas of Scotland or the UK. This may allow a larger target population to be studied with fewer ethical concerns.

The CIQ warrants further study as a marker of handicap and this could be conveniently studied using a postal questionnaire strategy aimed at a larger group. Future research could also address the practicalities of tracking the group of interest as they are difficult to identify many years after injury. A registry based approach may be useful.

8.12: Summary of discussion

Non-head injured survivors of major trauma treated in Glasgow hospitals more than two years previously:

- Are more impaired than suitable controls
- Have lower MCS scores in the SF36 than controls and the general UK population
- Have lower PCS scores than the UK and US populations
- Have little difference in employment status compared to controls
- Came from similarly deprived areas compared to controls

These findings are based on a small sample size, and therefore caution should be used when interpreting the findings.

The study does suggest that severe (non head) injury may not be highly disabling in the long term, which is rather counter-intuitive. It suggests that the current treatment services for this group of patients are appropriate in Scotland.

This small study also shows the difficulties of measuring long term outcomes from trauma in Scotland. The SF36 gave data which could be compared with UK values; comparisons with US data were also feasible.

The FIM added little due to ceiling effects, and given the necessity to visit patients and directly observe their abilities, makes it impractical for routine use. The CIQ did not show any significant differences, but sample sizes were small and further larger scale study may be warranted.

The AMA impairment score presents practical difficulties in terms of routine use, as it must be administered by a doctor and it relies upon hospital based specialist tests to assess some organ systems. It is too cumbersome for general use and could only be usefully used as a research tool. In addition, it may add little to the PCS component of the SF36 which is much easier to obtain.

The findings that the SF36 mental and physical summary scores are both decreased below the UK means suggest that further improvement could occur clinically in those areas. However, the high return to work rate and high FIM scores suggest that physical disability is not the major issue in terms of functional outcomes and current clinical management.

9: Conclusion

Non head injured survivors of major trauma in the West of Scotland have poorer health status (SF36), both in physical and mental terms, than the UK population. They have greater impairment (AMA impairment score), but have comparable employment status and deprivation status at least two years following injury compared to controls. There were no differences in FIM and CIQ scores between survivors and controls, but sample sizes were small.

A registry based cohort study design, concentrating on SF36, CIQ and return to work status, may shed further light on the outcomes of such patients in Scotland or the UK in the future.

10: Publication resulting from this work

A peer reviewed paper resulting from this work was published in early 2007 as reference below:

Graham C A, Gordon M W G, Roy C W, Hanlon P W. Long term outcomes of major trauma without head injury in the West of Scotland: case control study. *European Journal of Emergency Medicine* 2007;**14**:35-38.

Section B: Aspects of major trauma in Scotland

1: Blunt cervical spine injury in Scotland

Drainer E K, **Graham C A**, Munro P T.
Blunt cervical spine injuries in Scotland 1995-2000.
Injury 2003;**34**:330-333.

1.1: Summary

Background

In the emergency department, the management of patients who have sustained head injuries (HI) is often made more complicated by the suspicion of a cervical spine injury (CSI). This study aimed to evaluate the incidence of CSI in patients sustaining blunt head injuries in a Scottish population.

Methods

Retrospective analysis of prospectively collected data for a five-year period from the Scottish Trauma Audit Group (STAG) database. Logistic regression and other comparisons were used to investigate the relationship between Glasgow Coma Score (GCS) and the incidence of CSI.

Results

5 154 patients met the criteria for the study. 273 of the HI patients had associated CSI giving an overall incidence of 5.3%. Patients presenting with GCS 3 were almost three times more likely to have a CSI compared to patients with an initial GCS of 4 or more (12.5% v 4.4%, $\chi^2=62.9$, $df=1$, $p<0.001$).

When patients with GCS=3 were excluded, there was no evidence of an increase in the incidence of CSI with a lower GCS (logistic regression $\chi^2 = 0.09$, $df=1$, $p=0.75$).

Conclusion

The risk of CSI in patients with blunt head trauma and an admission GCS of 4 or greater does not decrease as GCS increases. Patients with blunt head injuries who present with a GCS of 3 are much more likely to have a concomitant CSI. The overall incidence of 5.3% compares with published series from other countries.

1.2: Introduction

Patients with head injuries form a significant part of the workload of any emergency department. Aside from the head injury itself, these challenging patients give rise to concerns due to the risk of concomitant cervical spine injury (CSI).

As CSI are not always initially obvious, Advanced Trauma Life Support (ATLS) guidelines recommend that all head injured patients with an injury above the clavicles should be assumed to have a CSI until proven otherwise (American College of Surgeons, 1999). An overall incidence of 5% is commonly quoted (American College of Surgeons, 1997).

The incidence of CSI varies considerably in the literature, ranging from 1.2% to 19% (Michael et al, 1989). Demetriades et al (2000) found that there was an

increasing number of CSI as the Glasgow Coma Scale (GCS) lowered, also suggested by Teasdale and Jennett (1974). Hills and Deane (1993) similarly showed a rate of 4.5% in head injured patients and 7.8% for patients in coma (defined as a GCS of less than or equal to 8). However, in contrast, O'Malley and Ross (1988) found no such correlation between the severity of head injury and the incidence of associated CSI.

Since airway management and cervical immobilisation are inextricably linked, it is important for physicians to be aware of the true incidence of CSI when clinically managing head injured patients. Airway control should not be compromised by overzealous spinal immobilisation (Shatney et al, 1995).

Davis (1993) found that 4.6% of CSI were missed; of those, nearly a third went on to develop permanent sequelae. Such oversights can be potentially devastating for the patients and their families. Up to 25% of trauma patients who attend with CSI suffer an extension of their injury due to careless and, at times, unnecessary manipulation (Banit et al 2000).

The aim of this study was to identify the incidence of CSI in patients who were admitted to hospital in Scotland after sustaining blunt head injuries.

1.3: Methods

This study was a retrospective analysis of a prospectively collected trauma database in Scotland assimilated by the Scottish Trauma Audit Group (STAG). STAG collects data on 98% of major trauma patients in Scotland. It receives

data from 25 hospitals, including four regional neurosurgical units and the Scottish national spinal injuries unit based in Glasgow (Beard et al, 2000). STAG utilises TRISS methodology (Boyd et al, 1987; American Association for Automotive Medicine 1990).

Patients are eligible for inclusion in the STAG database if they have sustained injuries secondary to trauma resulting in admission to hospital for three or more days or if they have died in hospital. Patients who arrive in cardiac arrest are included only if in-hospital resuscitation continues for longer than 15 minutes. Children under the age of 13 are not included.

This study used data for the period from 1 July 1995 until 30 June 2000.

Patients with massive crush injuries to the head were excluded as they are invariably lethal. Isolated vessel or nerve damage, minor scalp lacerations and pituitary injuries were not considered. Patients with brachial plexus injuries, nerve root injuries and minor soft tissue injuries were excluded.

Data for the five-year period was extracted from the STAG database.

Information was collected on the age and sex distribution of the patients, admission GCS, mechanism of injury, incidence of complete and incomplete spinal cord lesions, method of diagnosis of the CSI, ISS, initial destination from the emergency department and length of stay.

Outcome was defined in terms of survival or death within 90 days of admission. Data were analysed using SPSS for Windows v9 (Chicago, IL, USA). Logistic regression was used to investigate whether there was a systematic relationship

between GCS and the probability that a head-injured patient had a C-spine injury. The chi-square test was used to test between categorical variables. Statistical significance was defined as $p < 0.05$.

The records of head injured patients who attended the emergency department of the Southern General Hospital in September 1996 were examined to identify diagnosed neck injuries. This was to estimate the shortfall in overall incidence of CSI caused by the exclusion of minor and minimal head injuries from the STAG database.

1.4: Results

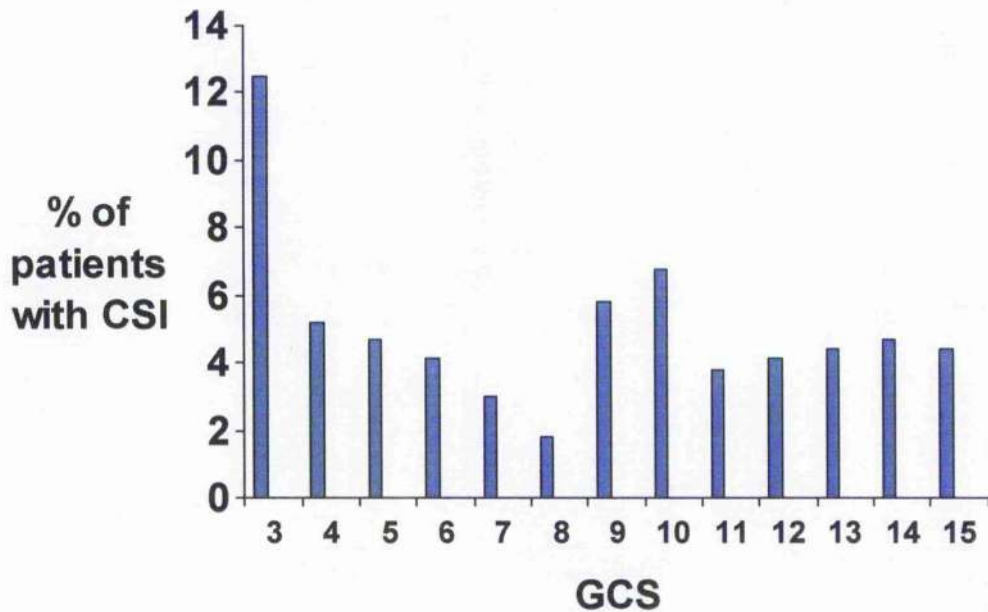
5 154 head injured patients were identified from the STAG database and a total of 273 patients had a concomitant CSI. The overall incidence of CSI in head injured patients was 5.3% (273/5154). Most head-injured patients with CSI were male (70%, 190/273) and there was a male preponderance in each age group except over 80 year olds. Both sexes showed peaks in early life (22% of males were 30-39 years old, 22% of females were 20-29 years old) and in later years (13% of males were 70-79 years old, 43% of females were over 70).

Figure B1.4.1 suggests that the incidence of CSI was greater in patients presenting with a GCS of 3. Excluding patients who were GCS 3, there was no evidence of a systematic decrease in the probability of having a C-spine injury with increasing GCS (logistic regression, $\chi^2=0.09$, $df=1$, $p=0.75$).

Figure B1.4.1

Incidence of CSI against Glasgow Coma Score

(Total n=5154, of whom 273 had CSI, an incidence of 5.3%).



However, patients who were GCS 3 were almost three times as likely to have a C-spine injury as patients who had a GCS between 4 and 15 (chi-square test with continuity correction: $\chi^2=62.9$, $df=1$, $p<0.001$). Despite the apparent variation in frequency of C-spine injuries in patients between GCS 8 and GCS 10, a chi-square test across all patients with a GCS between 4 and 15 indicated no significant variation (chi-square test: $\chi^2=6.63$, $df=11$, $p=0.83$).

When the head injuries are divided into minor (GCS 13-15), moderate (GCS 9-12) and severe (GCS ≤ 8), the incidence of associated CSI is 4.5% (146/3247), 5% (30/597) and 7.4% (97/1310) respectively.

Mechanisms of injury are detailed in Table B1.4.1.

Table B1.4.1

Mechanism of injury of patients with head injuries and associated CSI

	Number of HI patients with CSI	% of all CSI patients	% (n) of HI patients with a CSI
MVC	157	57.5%	8.2% (157/1922)
Fall >2m	55	20.1%	8.1% (55/679)
Fall <2m	43	15.8%	3.5% (43/1227)
Other	10	3.7%	2.6% (10/385)
Assault	5	1.8%	0.6% (5/892)
Sport	3	1.1%	6.1% (3/49)
Total	273	100%	5.3% (273/5154)

After allowing for GCS, head-injured victims of motor vehicle crashes and high falls were more than twice as likely to have an associated CSI than patients with other mechanisms of injury (for GCS 3, $\chi^2=18.5$, $df=4$, $p=0.001$; for GCS 4-15, $\chi^2=63.5$, $df=4$, $p<0.001$).

The definitive diagnostic modalities for CSI are shown in Table B1.4.2.

Table B1.4.2

Definitive diagnostic source of CSI

	Frequency	%
CT	122	44.7
Autopsy	73	26.7
Radiography	66	24.2
MRI	6	2.2
Clinical	6	2.2
Total	273	100

Fractures and dislocations of the cervical spine without cord injury were most common, occurring in 4.2% (216/5154) of the head injured population. Cord contusions and lacerations were found in 1.1% of patients (57/5154).

Table B1.4.3 demonstrates the number of patients with complete cord syndrome (defined as quadriplegia or paraplegia with no sensory or motor function irrespective of associated cervical spine injury) and incomplete cord syndrome (defined as preservation of some sensation and/or motor function, again irrespective of type of injury).

Table B1.4.3

Complete, incomplete & transient cord syndromes

GCS	Complete	Incomplete	Transient	Not further specified	Total
3-8	12	1	4	3	20
9-12	4	0	1	2	7
13-15	8	8	14	0	30
Total	24	9	19	5	57

A transient neurological deficit was defined as a deficit which was present on admission but which had resolved completely by the time of discharge (personal communication, Scottish Trauma Audit Group). Comparison of neurological deficit and the individual's Injury Severity Score are as shown in Table B1.4.4.

Table B1.4.4

Cord syndrome by injury severity score (ISS)

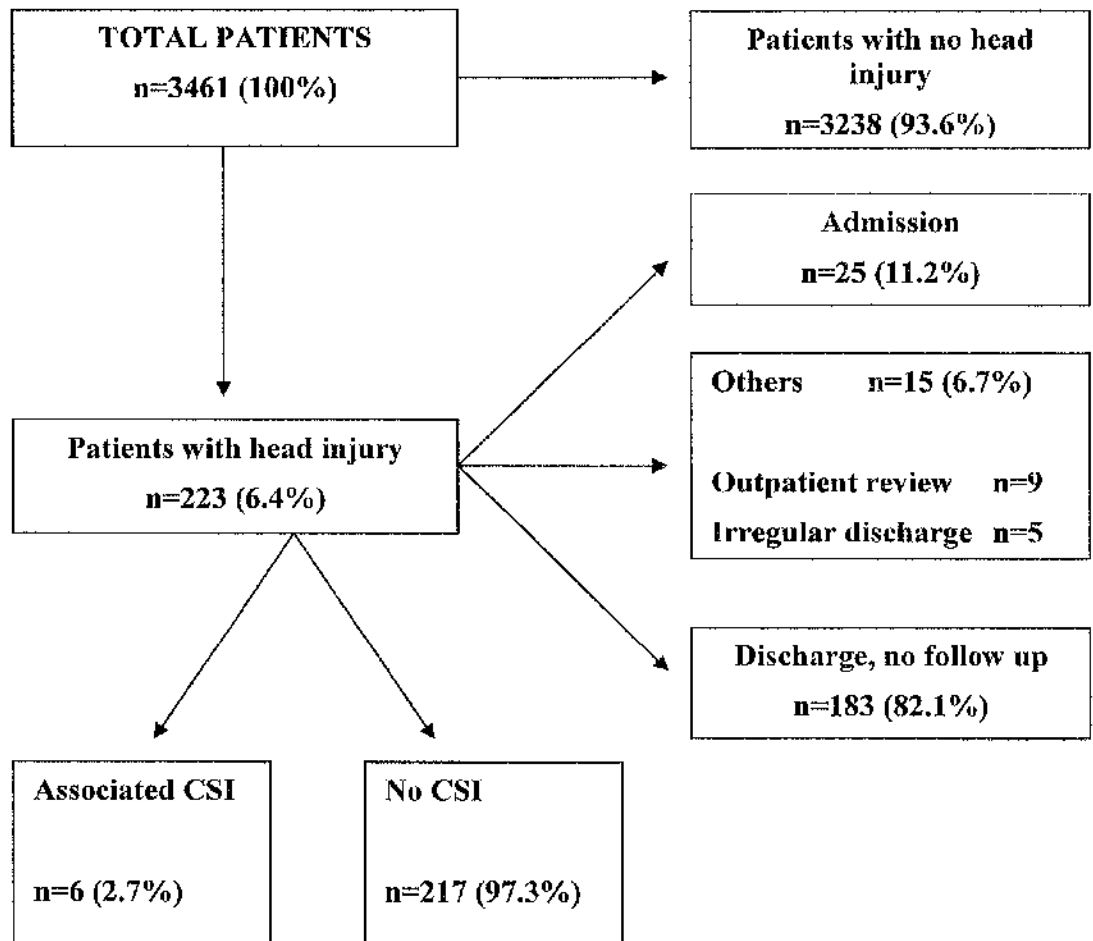
	Transient	Incomplete	Complete
ISS 9-15	12	0	0
ISS 16-24	1	8	0
ISS 25-49	4	1	13
ISS 50-75	2	0	11
Total	19	9	24

Overall, 65.2% (178/273) of the CSI patient group survived and 34.8% (95/273) died. 27.5% (75/273) of patients died within three days of admission and 28.6% (78/273), remained in hospital for 1-3 months. 34.1% (93/273) went to a general ward, while 23.1% (63/273) were transferred to a neurosurgical unit.

9.9% (27/273) of CSI patients went directly to theatre and 13.2% (36/273) died in the emergency department. The results of the retrospective departmental head injury analysis for CSI are shown in Figure B1.4.2.

Figure B1.4.2

Southern General Hospital emergency department admissions September 1996



1.5: Discussion

This study has shown that, across the entire spectrum of head injured patients, the incidence of CSI in patients with a GCS of 3 is significantly higher than those patients with a GCS of greater than or equal to 4. When patients with a GCS of 3 are excluded, there is no correlation between the severity of head injury and the occurrence of CSI.

It should be remembered that patients with a head injury resulting in a GCS of 3 represent a spectrum of illness ranging from alcohol intoxication to cardiac arrest. When conventional definitions of severity of head injury based on GCS are used, this study confirms the excess risk of CSI in patients with severe HI (GCS 3-8). However, it is clear from Figure B1.4.1 that the incidence of CSI is equally distributed between all patients with GCS 4 to GCS 15.

Therefore in Scotland approximately one in twenty head injured patients admitted to hospital will have an associated CSI and it is impossible to predict which individuals will have a CSI on the basis of GCS alone. As the majority of head injuries tend to be minor ones not requiring admission or admission for less than three days, our study will have over estimated the percentage of patients with CSI within the minor HI group (GCS 13-15).

The historical cohort of head injured patients detailed in Figure B1.4.2 shows an incidence of "neck injury" of 2.7% (6/223), but this is likely to overestimate the true incidence of CSI in this population as muscular injuries will be included in

this group. In keeping with previous work, road traffic accidents and high falls were significantly more common as causes of CSI (Prasad et al 1999).

Computed tomography (CT) was the most commonly used modality for definitively diagnosing CSI. Magnetic resonance imaging (MRI) was used in only 2.2% (6/273) of patients. This result supports the study by Patton et al (2000), which suggested that the chance of ligamentous injury is so small that CT scanning and cervical spine radiographs are the only tests required to diagnose the majority of CSI. MRI scanning should be reserved only for those who remain symptomatic despite normal plain radiography and CT. Experience with dynamic fluoroscopy is limited (Brohi and Wilson-Macdonald, 2000; Davis et al 2001).

It may be useful in the future to look at the incidence of CSI in all head injured patients. Our results can be applied to a patient population with more serious head injuries resulting in admission or death. The inclusion of patients with minor head injuries may alter the lack of correlation between GCS and CSI.

We conclude that the incidence of an associated CSI in patients in Scotland who require admission to hospital following a significant head injury is 5.3%. Patients who are GCS 3 are more likely to have an associated CSI compared to those with a GCS greater than or equal to 4.

2: Penetrating spinal injury in Scotland: is spinal immobilisation required?

Connell R A, Graham C A, Munro P T.

Is spinal immobilisation necessary for all patients sustaining isolated penetrating trauma?

Injury 2003;**34**:912-914.

2.1: Summary

Background

Previous work suggests that patients with isolated penetrating trauma rarely require spinal immobilisation. This study aimed to identify the incidence of mechanically unstable, or potentially mechanically unstable, spinal column injuries in penetrating trauma patients. The study also aimed to identify the incidence of spinal cord injury as a result of penetrating trauma in Scotland.

Methods

Retrospective analysis of prospectively collected data from the Scottish Trauma Audit Group (STAG). Study patients were identified from the period 1992 – 1999. Patients coded for both penetrating trauma and spinal column or spinal cord injury were included. Case records, theatre notes and post mortem information were also examined.

Results

34 903 patients were available for study. 27 patients were coded as having had penetrating trauma and concurrent spinal injury. 15 were excluded as they also had a major blunt mechanism of injury or had no actual injury to the spinal cord

or column. In the remaining 12 patients, four cervical, one combined cervical and thoracic and seven thoracic spinal cord injuries were identified. 11 were male and 11 were assaulted. One assault was due to a gunshot wound; 10 resulted from sharp weapons. Four complete cord transections and nine partial cord lesions were identified. All 12 patients with spinal cord injury associated with isolated penetrating trauma either had obvious clinical evidence of a spinal cord injury on initial assessment or were in traumatic cardiac arrest. All had spinal immobilisation.

Conclusion

Fully conscious patients (GCS=15) with isolated penetrating trauma and no neurological deficit do not require spinal immobilisation.

2.2: Introduction

It has been suggested that full spinal immobilisation is rarely, if ever, required for patients with isolated penetrating trauma (Barkana et al, 2000; Cornwell et al, 2000). The ATLS (Advanced Trauma Life Support) student manual does not make the distinction between blunt and penetrating trauma with regards to spinal injury (American College of Surgeons, 1997).

It emphasises the need for full and continuous spinal immobilisation in any patient with a suspected spinal cord or column injury until a fracture has been radiologically excluded. This refers predominantly to blunt trauma of the spinal cord and spinal column.

This approach has significant implications for pre-hospital care. Time may be a crucial factor in determining outcome in severe penetrating trauma. In critically injured patients, it has been estimated that for every 10 minutes of delay in definitive treatment, survival drops by 10% (Demetriades et al, 1996).

Therefore, in this study we aimed to determine if there were any mechanically unstable or potentially mechanically unstable spinal column injuries requiring formal spinal immobilisation in isolated penetrating trauma patients in Scotland. We also examined the incidence of spinal cord injury due to penetrating trauma in Scotland.

2.3: Methods

The Scottish Trauma Audit Group (STAG) was established in 1991 to evaluate the management of major trauma in individual Scottish hospitals (Beard et al, 2000). It utilises TRISS methodology, which combines the Injury Severity Score (ISS) and the Revised Trauma Score (RTS) in addition to the patient's age, to generate a probability of survival for each patient (Boyd et al, 1987). 25 hospitals contributed to the national database. At the time of the analysis, data had been collected prospectively on more than 34 000 patients.

The entry criteria for patients onto the database are all trauma patients who are in-patients for three days or more, patients who die as a result of trauma, or patients who are transferred to a regional or national specialist service. This captures approximately 98% of seriously injured patients in Scotland.

Study patients were identified from the period 1992 – 1999. Patients coded for penetrating trauma and spinal column or spinal cord injury were included in the study. Copies of the original STAG forms were made available for data collection and, if further information was required, it was obtained from individual case records, theatre notes and post mortem information.

2.4: Results

34 903 trauma patients were available for study; 32 974 (94.5%) had sustained blunt trauma and 1 929 (5.5%) penetrating trauma. 27 patients were coded as having penetrating trauma and concurrent spinal injury.

15 patients were excluded either because initial review clearly showed that there was a major blunt mechanism of injury also coded which unequivocally caused the spinal trauma, or because the spinal component of the injury was trivial. Patients were also excluded if there were discrete injuries affecting the peripheral nerves and nerve roots distal to the spinal column but where there was no injury to the spinal cord or column identified.

In the remaining 12 patients there were four cervical and seven thoracic spinal cord injuries. One patient had both a cervical and thoracic cord injury. There were no documented injuries to the lumbosacral spine.

11 patients were male and all but one had been assaulted, the other being an industrial accident. One assault was due to a gunshot wound (GSW) and the others resulted from sharp weapons.

Four complete transections of the spinal cord were identified along with nine partial cord lesions. Three of these patients presented with a classic Brown-Séquard syndrome: lateral hemisection of the spinal cord producing ipsilateral paralysis (corticospinal tract) and loss of joint position sense (posterior column) below the lesion with contralateral loss of pain and temperature sensation (spinothalamic tract).

All 12 patients who sustained spinal cord injury associated with isolated penetrating trauma had either obvious clinical evidence of a spinal cord injury on initial assessment or were in traumatic cardiac arrest (n=2). All had full spinal immobilisation instituted.

2.5: Discussion

In 1 929 cases of penetrating trauma, the only patients with spinal cord lesions had clear evidence of this at initial presentation or were in cardiorespiratory arrest. This suggests that spinal column or spinal cord injury resulting from isolated penetrating trauma can be excluded in fully conscious patients without neurological symptoms or signs at presentation.

Contemporary teaching on trauma does not make any distinction between blunt and penetrating trauma in terms of the need for full spinal immobilisation.

Recent studies have questioned the importance of full formal spinal immobilisation in patients with isolated penetrating trauma (Barkana et al, 2000; Cornwell et al, 2000; Demetriades et al, 1998; Kaups and Davis 1998). This is based on the belief that spinal stabilisation in the pre-hospital setting would prolong on scene times and make airway manoeuvres unnecessarily difficult.

Demetriades et al (1996) compared 4 865 EMS (Emergency Medical Services, i.e. ambulance transported) patients with 926 non-EMS (friends, relatives, bystanders or police transported) patients. The two groups had similar mechanisms of injury.

Subgroup analysis showed that ISS >15 patients in the EMS group had a mortality of 28.8% vs. 14.1% in the non-EMS group. The authors concluded that patients with severe trauma transported by private means in this setting were more likely to survive and that longer pre-hospital times in the ambulance group may have been an important factor in this. It is suggested that patients brought in by bystanders reach the hospital for definitive treatment more than 30 minutes earlier than those brought in by EMS methods.

Lerer and Knottenbelt (1994) in a report from South Africa demonstrated that the survival rate following penetrating chest trauma was better in patients from poorer socio-economic areas. The authors of the study speculated the use of more readily available private transportation to reach the hospital among poorer patients might explain the outcome difference. This observation appears particularly true for penetrating cardiac injuries (Buckman et al, 1993; Gervin and Fischer, 1982).

Recently, there have been concerns expressed on the value of pre-hospital interventions made by paramedics on patients and the appropriateness of prolonged on scene times incurred (Demetriades et al, 1996; Rainer et al, 1997).

Cornwell et al (2000) further analysed the patient group identified by Demetriades et al (1996) and observed that there was not even one, of more than 3 000 patients with penetrating trauma in this study, who even theoretically benefited by formal thoracolumbar immobilisation.

Kaups and Davis (1998), in a study investigating the appropriateness of cervical spine immobilisation and evaluation in patients with traumatic gunshot wounds to the head, concluded that indirect (blast or fall related) spinal injury does not occur in patients with gunshot wounds to the head.

Their figures showed that unsuccessful attempts at intubation were closely associated with patients in cervical spine immobilisation. They concluded that protocols mandating cervical spine immobilisation after a GSW to the head were unnecessary and may compromise airway management.

This theory was reinforced by Barkana et al (2000). In a retrospective study of 44 military casualties with a penetrating neck injury over a 4.5 year period, they found no cases where surgical stabilisation of a mechanically unstable cervical spinal column injury was required. They concluded that it is extremely rare for a penetrating injury to result in a mechanically unstable cervical spine.

It was noted that of the 44 cases studied most injuries were due to projectiles or bullets. This contrasts with our study where the majority of injuries to the spinal cord (10 out of 12 patients) were from sharp weapons in assaults.

Barkana et al (2000) also highlight that life threatening complications of penetrating neck injury (large or expanding haematoma, tracheal deviation, subcutaneous emphysema and diminished or absent carotid pulsation) are often manifest as visible or palpable signs in the neck and that these may be missed if the neck is obscured by a device such as a semi-rigid collar.

In their study, 22% of trauma victims developed one or more of the above signs either in the pre-hospital or emergency department setting.

However, a further study by Demetriades et al (1998) showed that 8% of a population of 247 patients with a GSW to the face also had a cervical spine injury. The authors suggest that formal spinal immobilisation is indicated in patients with a GSW to the face if there is any suspicion of the bullet trajectory traversing the neck, if no exit wounds are evident, or if the patient has focal neurological deficit suggestive of spinal cord injury.

These conclusions appear equally valid when applied to GSWs to the head (Kaups and Davis, 1998), although our data does not allow us to comment on the risks of spinal cord injury associated with GSWs as we had only one such case in this series.

Our study also found that the majority of patients who had a definite spinal cord injury had neurological symptoms or signs suggestive of a spinal lesion at presentation. The remainder were in traumatic cardiac arrest.

Barkana et al (2000) analysed the definitions of mechanical spinal instability and the stability scoring systems applied to determine the extent of spinal integrity (two- and three-column theories). Although these systems were designed for blunt trauma, if they are applied to penetrating trauma, it is very rare to find a biomechanically unstable spinal injury.

The authors propose that it is unlikely for penetrating injury to cause substantial spinal damage leading to instability without completely destroying the cord, causing a permanent, irreversible neurological deficit.

Our study agrees with the evidence above and therefore we suggest making distinctions between recommendations for the management of spinal immobilisation in blunt and penetrating trauma. This would avoid excessive pre-hospital times and unnecessary difficulties with emergency airway interventions in patients with isolated penetrating trauma.

Spinal immobilisation is not required in fully conscious patients (GCS 15) with isolated penetrating trauma unless there is any obvious neurological deficit at presentation.

3: Mortality following trauma intubation without drugs in Scotland

Graham C A, Wares G M, Munro P T.
Mortality after trauma intubation without drugs in Scottish emergency departments.
Resuscitation 2006;**69**:395-397.

3.1: Summary

Background

Trauma patients who are intubated without anaesthetic drugs in the pre-hospital phase of care have universally poor outcomes. This study aimed to determine the mortality of trauma patients intubated without drugs in emergency departments in Scotland.

Methods

This retrospective cohort study used the prospective Scottish Trauma Audit Group database to identify how many patients were intubated and how many required drugs for intubation between 1 January 1999 and 31 December 2002. The mortality of those intubated with drugs and without drugs was determined from the database.

Results

24 756 patients in the STAG database, 1 469 intubations: 1 287 with drugs and 182 without drugs. 92.5% of intubations were for blunt trauma. No difference in the proportion of males or median age between groups. Median GCS was 8 (E1M5V2) in the drugs group and 3 (E1M1V1) in the no drugs group ($p < 0.001$).

Median ISS was higher in those intubated without drugs (33 v 25, $p<0.001$). Median RTS and probability of survival were lower in those intubated without drugs (both $p<0.001$). Mortality was higher in those intubated without drugs (91.2% v 29.4%, $p<0.001$). 16 patients, intubated without drugs, survived. These patients had a higher median respiratory rate (9 v 0, $p=0.013$) and higher median systolic blood pressure (80mmHg v 0, $p=0.041$) than non-survivors.

Conclusion

Trauma patients in Scottish emergency departments who are intubated without drugs have high mortality rates. Outcomes are not universally fatal and aggressive resuscitation efforts may be of benefit to a small number of such patients.

Keywords

Intubation; anaesthesia; drug therapy; outcome; trauma.

3.2: Introduction

Effective airway management is the cornerstone of major trauma management (Walls 1998). Endotracheal intubation is regarded as the gold standard for airway management in the emergency department (ED) for trauma patients who have a Glasgow Coma Scale (GCS) score ≤ 8 (American College of Surgeons 1997). Previous work from the United Kingdom (Lockey et al 2001) and Denmark (Christensen and Hoyer 2003) has shown the futility of endotracheal intubation without drugs in the prehospital setting for patients with trauma.

Experience and anecdotal evidence suggests that trauma patients who can be intubated without anaesthetic drugs in the ED have a poor outcome. The aim of this study was to investigate the mortality of trauma patients who were intubated without drugs in the ED setting in Scotland.

3.3: Methods

The Scottish Trauma Audit Group (STAG) database prospectively collected data on the majority of trauma patients reaching hospital alive in Scotland between 1992 and 2002. Data has been collected on endotracheal intubation in the ED since 1998 (Graham et al 2003). This data included whether or not the patient was intubated; speciality of the intubator; use of anaesthetic drugs; GCS score on ED admission; physiological variables (respiratory rate, systolic blood pressure); mortality (patients were followed up to hospital discharge or survival up to 92 days following admission).

Patients were prospectively entered on to the STAG database if they were admitted to hospital following trauma for more than two days, or if they were admitted to an intensive care unit, operating room, regional neurosurgical centre or the national spinal injuries unit. Patients who died after admission to hospital following trauma were included, but those who died within 15 minutes of arrival in the ED were excluded. Patients who had sustained burns, smoke inhalation, drowning or hanging were specifically excluded from the STAG database.

This retrospective cohort study used the STAG database to identify how many patients were intubated and how many required drugs for intubation. The study period was from 1 January 1999 to 31 December 2002.

The mortality of those intubated with drugs and those intubated without drugs were determined from the database.

Statistical analyses were performed using the chi square test for categorical data and the Mann-Whitney U test for non-parametric data (ISS, GCS).

3.4: Results

During the four year study period, 24 756 patients were enrolled into the STAG database. 1 469 patients were intubated, 1 287 (87.6%) with drugs and 182 (12.4%) without drugs.

1 359 intubations (92.5%) were for blunt trauma. The two groups were comparable in terms of age and sex as shown in Table B3.4.1.

Table B3.4.1

Mortality of intubated trauma patients in Scotland 1999-2002

	Intubated with anaesthetic drugs (n=1 287)	Intubated without anaesthetic drugs (n=182)	p
Males	1042/1287 (81.0%)	153/182 (84.1%)	0.4
Median age (years)	38	35	0.3
Median total GCS (IQR)	8 (4-12)	3 (3-3)	p<0.001
Median GCS eye (IQR)	1 (1-4)	1 (1-1)	p<0.001
Median GCS motor (IQR)	5 (2-5)	1 (1-1)	p<0.001
Median GCS vocal (IQR)	2 (1-4)	1 (1-1)	p<0.001
Median injury severity score (IQR)	25 (16-30)	33 (26-48)	p<0.001
Mortality	378/1287 (29.4%)	166/182 (91.2%)	p<0.001

16 patients (8.8%, 95% CI 5.1%-13.9%) who were intubated without drugs did survive. Compared with those that died, survivors had a higher median respiratory rate (9 v 0, $p=0.013$) and higher median systolic blood pressure (80mmHg v 0, $p=0.041$) on ED arrival.

Of 151 patients who were GCS 3 on arrival and were intubated without drugs, 13 survived (8.6%). The survivors had higher median systolic blood pressure (112mmHg v 0, $p=0.013$), higher median respiratory rate (12 v 0, $p=0.003$), higher oxygen saturation (92% v 0, $p=0.044$) and higher median injury severity score (33 v 17, $p<0.001$).

No combination of vital signs was found to correlate with certain death.

3.5: Discussion

8.8% of patients intubated without drugs in the ED following trauma survived in our study. Previous studies in prehospital settings (including physician and paramedic intubation) have suggested that fewer patients survive (95% CI 0.2%-8%).

It is possible that there is a population of severely injured patients who reach the ED at the limit of physiological compensation who may benefit from aggressive resuscitation.

Although trauma patients who are intubated without drugs have a demonstrably high mortality, this study suggests that intensive resuscitation efforts in the ED may yield occasional survivors.

The limitations of this study include the fact that the STAG database recorded only mortality, and not morbidity, and data is lacking on the functional outcome of these survivors.

The anonymous nature of the database does not allow the identification of any common factors that may predict the survival of certain individuals; this would require further prospective study on a large scale.

It is certainly possible that some of these survivors may have been under the influence of recreational drugs or alcohol, which may have made it possible to intubate these patients without anaesthetic drugs, but again the anonymous database does not allow further exploration of this possibility.

Trauma patients who are intubated without drugs have a very high mortality, but it suggests that intensive resuscitation efforts in the ED may yield occasional survivors in this critically injured population.

4: Children's injuries in a Scottish district general hospital

Graham C A, McDonald A, Stevenson J.
Children's injuries in a Scottish district general hospital.
Injury 2005;36:1040-1044.

4.1: Summary

Background

Injury is a common cause of emergency department (ED) attendance but there are few data published on the spectrum of injury in a typical district general hospital (DGH). This study aimed to provide a complete picture of injury presentations to such a centre.

Methods

Prospective questionnaire study of consecutive paediatric attendances at a DGH ED in Scotland (annual attendance 53 500 patients) due to injury or poisoning. Paediatric in this context was defined as less than 14 years on the day of presentation. Admission rates were identified from the hospital information system and information on deaths was sought from the local Procurator Fiscal (the Scottish equivalent of the Coroner).

Results

1 378 questionnaires were completed from a potential 10 697 eligible patients. Safety devices (helmets, belts, etc.) were in use in only 99 cases. Cycle helmets were used in 26% of cycle incidents and seat belts were used in 71% of car incidents. Cycling and pedestrian incidents were more common during

the summer months and outside school hours. Adult supervision was present in 49% of incidents. 73% of incidents at school were unsupervised. There were 5.6 admissions to hospital per day in the 0-13 year age group for all causes, with little seasonal variation in admission rates. There were three deaths during the year, two from sudden infant death syndrome (SIDS) and one due to choking, all in infants.

Conclusion

Trauma is a common cause of ED attendance in children. Preventative measures are still underutilised and could make a significant impact on the incidence of children's injuries and possibly ED attendances. Cycle helmets could play a major role in injury prevention in school age children in this area.

4.2: Introduction

Children's injuries are very common (Stone and Doraiswamy 1996; Stone and Morrison 1998) and form a large proportion of the workload of Emergency Departments (ED) in the United Kingdom (UK) (Stone and Doraiswamy 1996; Kemp and Sibert 1997) and elsewhere (Brudvik 2000). Injury surveillance systems have been used throughout the world, most notably the Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) system (Canadian Hospitals Injury Reporting and Prevention Program 1994; Stone and Doraiswamy 1996), which has been used successfully in a Scottish setting (Kemp and Sibert 1997).

However, there are few data available on the epidemiology of children's injuries in a "typical" district general hospital (DGH) setting in the UK. It would be useful from crash prevention, public health and emergency medicine service provision viewpoints to have an epidemiologically complete study of children's injuries in a DGH setting in the UK.

The aim of this descriptive study was to define a complete picture of typical children's injuries as seen in a UK district general hospital setting and to assess the factors surrounding such injuries in the ED setting.

4.3: Methods

The study consisted of a prospective observational questionnaire study of all patients less than 14 years of age (on the day of presentation) attending the ED of Crosshouse Hospital, Kilmarnock, Scotland. This DGH has 562 beds, including 48 beds specifically for children. The ED sees around 53 500 patients annually. Crosshouse Hospital serves a mixed urban/rural community with an estimated population at the time of the study of 240 000 individuals.

All ED staff were informed of the aims and objectives of the study prior to it starting by means of a written information leaflet. Patients were deemed eligible for the study if they were less than 14 years of age on the day of attendance at the ED and they were attending the ED with an acute traumatic condition secondary to a recent injury.

A simple, one page questionnaire (Figure B4.3.1) was given to each patient and their parent or guardian on arrival at the ED triage room and they were given verbal information about the study. Verbal consent was sought and, if obtained, the questionnaire was completed by the patient and/or guardian while waiting to see the ED doctor.

Figure B4.3.1

Questionnaire: Children's Injuries Form

Please complete this form about your child's injury

(this includes children who have taken too much medicine, etc.)

This will help us to develop methods of preventing such injuries occurring in the future.

1 When did the incident happen?

Day

Date

Time

2 Was an adult with the child when the incident happened?

Yes / No

3 What was the child doing when the incident happened?

(e.g. on bicycle; ice skating; playing in house; travelling in car; etc.)

4 What happened? (e.g. fell off bike; car accident; hot coffee spilled; etc.)

5 What safety precautions (if any) were in use when the incident happened? (e.g. car safety seat; cycle helmet)

The duty medical or nursing staff in general answered any questions regarding the questionnaire or the study and assistance was offered in cases of difficulty of comprehension or reading or writing.

Completed questionnaires were retrieved by medical or nursing staff and collected for analysis. Data collection started on 1 September 1999 and continued until 31 August 2000. The number of paediatric patients who were admitted to hospital per month was identified from the hospital information system.

In addition, an approach was made to the local Procurator Fiscal for information on any traumatic deaths in the area served by the hospital during the period of the study. The Procurator Fiscal is the legal authority in Scotland who has legal responsibility for investigating any sudden or unexplained deaths (similar to the Coroner in England and Wales). Deaths were identified and classified according to causation and location.

Injuries, mechanisms of injury and other data were classified into categories for analysis. All data obtained from the study were entered on to the SPSS statistical package v9.0 for analysis. Fisher's exact test was used and statistical significance was taken as $p < 0.05$. Ethical approval for the study was obtained from the Ayrshire and Arran Health Board Ethics Committee.

4.4: Results

The study period extended from 1 September 1999 to 31 August 2000. During that time, a total of 53 585 patients were seen in the ED. Of these, 10 697 patients were eligible for the study as defined above.

The number of completed questionnaires was 1 378, giving a completion rate for the questionnaires of 12.9%.

The number of patients presenting per month is shown in Figure B4.4.1 along with the number of completed questionnaires per month.

Figure B4.4.1

Number of presenting eligible patients, number of completed questionnaires and number of hospital admissions per month

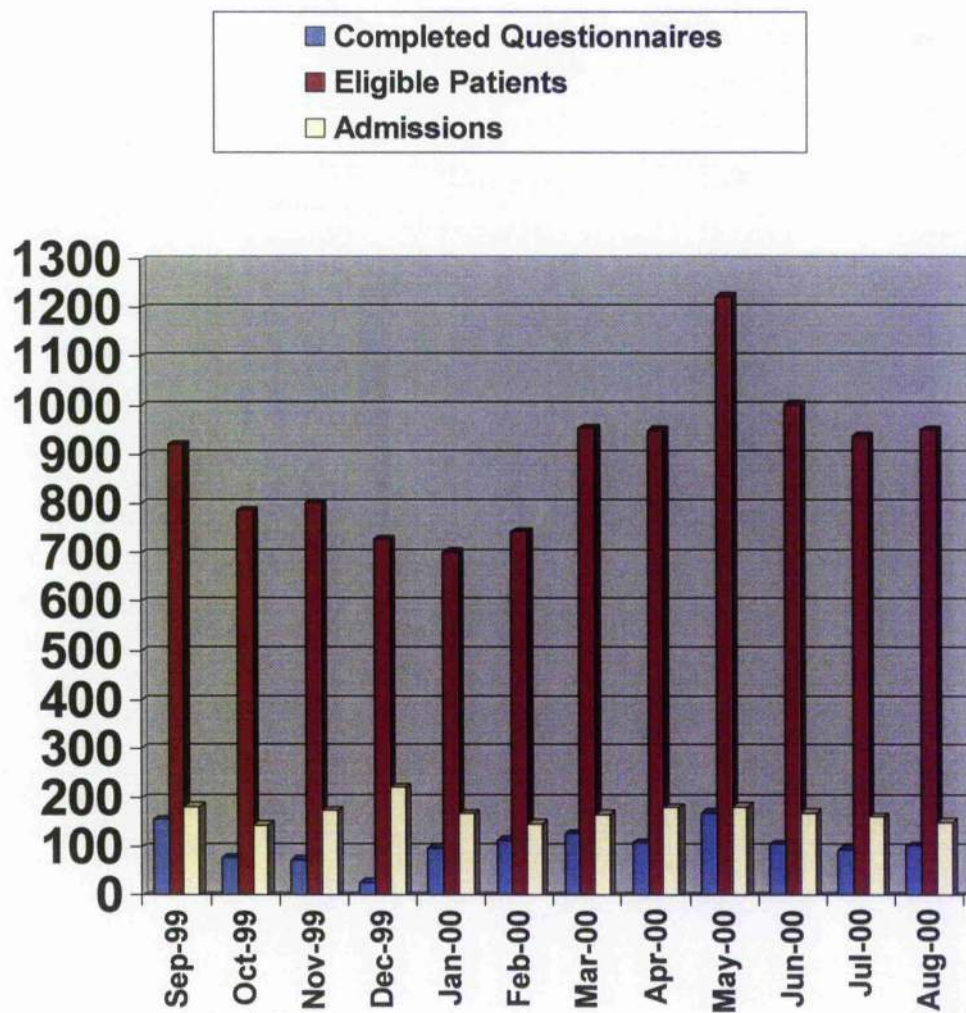
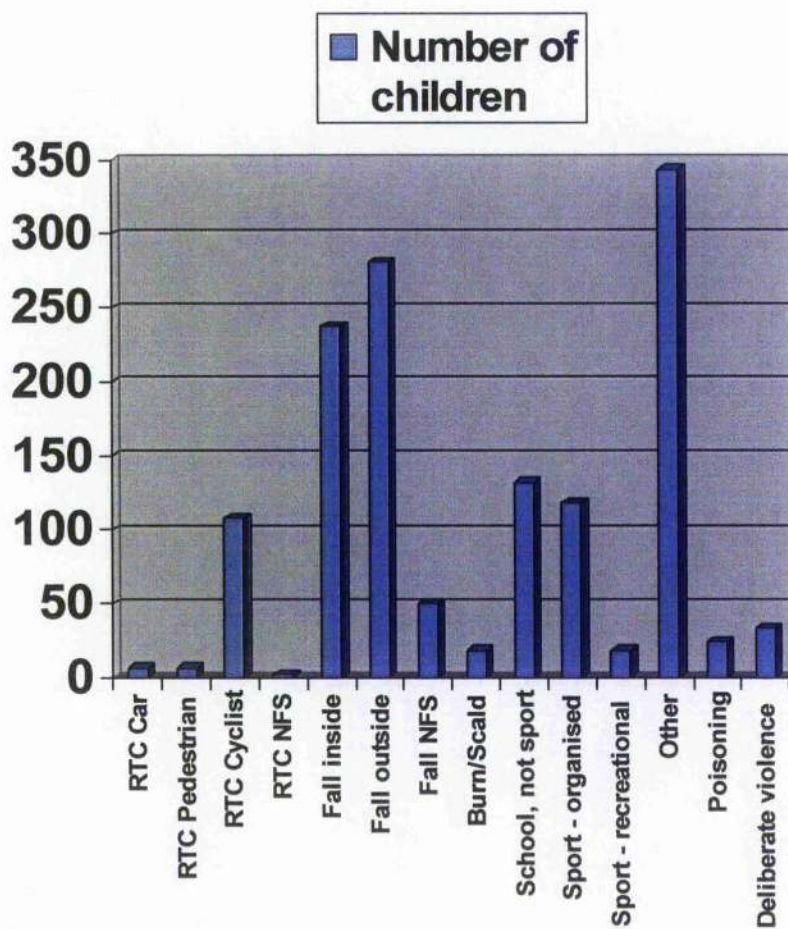


Figure B4.4.2 shows the types of incident over the period of the entire study.

Figure B4.4.2

Type of incident



RTC: road traffic crash
NFS: not further specified

In only 99 (7.2%) instances were any safety measures in use. These included cycle helmets (28 instances), safety belts (16 instances), protective pads (36 instances), childproof containers (1 instance) and 18 other unspecified safety

measures. In contrast, there were 108 cycling incidents, 281 incidents involving a fall outside and 118 incidents involving organised sport and 24 episodes of poisoning.

Cycle helmets were only in use in 26% (28/108) of cycle road traffic crashes. In contrast, seat belts were in use in 5 of 7 road traffic crashes involving cars ($p=0.02$, Fisher's exact test).

Cycling crashes and pedestrian road traffic crashes were more common outside school hours (66/92 and 5/6 respectively) and were more common during the summer months (April to September).

Adults were present with children in around half of all incidents (670/1353, 48.6%). The majority of cyclists involved in crashes were not supervised by an adult (94/106, 88.7%).

Falls inside buildings usually occurred when an adult was present (168/234, 71.7%) and the majority of those falling were of pre-school age (154/236, 65.3%).

Falls inside buildings occurred more frequently during the winter months. In contrast most falls outside were unsupervised (169/277, 61.0%; $p<0.0001$ for adult supervision, Fisher's exact test) and those falling were of school age (212/281, 75.4%).

73% (95/130) of school incidents occurred when children were unsupervised. Preschool children were more often scalded or burned compared to older children (11 preschool children v 7 school age children) and were more often victims of poisoning (21 preschool children v 3 school age children). Deliberate violence was associated strongly with school age children (30/33, 90.9%).

4.4.1: Admissions

In the 0-5 years age group, there were 1 282 emergency admissions to hospital (724 male admissions; 557 female admissions; one admission where sex was not recorded).

In the 5-13 years age group, there were 772 emergency admissions (471 males, 301 females). This equates to an admission rate of 3.5 children under 5 years old per day and 2.1 children aged 5-13 per day, a total of 5.6 children under the age of 14 per day.

4.4.2: Deaths

We identified three deaths in this age group in the year in question. Two of these were infants with sudden infant death syndrome and one infant presented in cardiac arrest secondary to choking, was initially resuscitated but subsequently died.

The Procurator Fiscal reported that there were no paediatric trauma deaths during the study period.

4.5: Discussion

Trauma remains a common cause of attendance at the ED and a common cause for admission to hospital in the 0 to 13 year age group. The commonest reasons for injury are falls, sports, cycling, school incidents and a miscellaneous mix of unclassifiable aetiologies ("other"). Some of these injuries may be amenable to preventative measures.

It is disappointing to note the high number of cycling incidents, most of which occur without any protective measures in place, such as cycle helmets. The low prevalence of use of helmets may be contributing to the injuries and morbidity sustained by children in this area.

In contrast, seat belts were used in a high proportion of incidents where children were injured in road traffic crashes, although this proportion could be increased further through education and enforcement of the seat belt legislation.

The lack of adult supervision may also play a key role in the aetiology of some of these incidents. While there has to be a balance between adult supervision, giving children responsibility, and the practicalities of real life, it is possible that some of the injuries seen may have been preventable by better adult supervision of children's activities.

This may especially apply to some school incidents, where 73% of injuries occurred in unsupervised children and to falls outside, where the majority of

injuries were unsupervised and in children of school age (5-13 years). These data are consistent with previous UK data on school incidents (Maitra 1997).

In addition, the majority of deliberate violence occurred against school age children; this suggests that improved adult supervision at school might have an impact on this finding, although this remains speculative.

The hospital admission pattern is fairly constant throughout the year. The increased incidence of injury during the summer months may offset the reduction in medical admissions which are more common in the winter months.

The questionnaire completion rate for the study was disappointingly low. This was despite staff education, frequent reminders to collect data and positive feedback to staff within the department.

The fact remains that there were no dedicated staff appointed to collect data for the study, and data collection relied on individual staff being able to distribute and collect forms to appropriate patients, often when staff numbers were low and the ED was very busy.

For future studies of this nature it would be prudent to appoint a specific research assistant to coordinate and manage data collection to maximise the chances of a high data capture rate. Again this is consistent with the findings of the CHIRPP implementation study in Scotland, which also commented on the need for enhanced staff provision to support the data collection function (Stone and Doraiswamy 1996).

This study gives a picture of the range and frequency of injuries seen in children under the age of 14 in a typical Scottish DGH emergency department.

Prevention continues to be underutilised and should be emphasised by public health authorities, emergency department staff and those in contact with children and parents, such as nursery and school staff.

Cycle crashes and adult supervision may be appropriate initial specific targets for preventative measures. Specifically, the low rate of helmet use in the current study is of concern and could be a major target of any future preventative strategy, especially for the school age group (5-13 years) which makes up the majority (84%) of the cyclists injured in this study.

The widespread adoption of universal cycle helmet use should be vigorously pursued.

5: Rapid sequence intubation of trauma patients in Scotland

Graham C A, Beard D, Henry J M, McKeown D W.
Rapid sequence intubation of trauma patients in Scotland.
Journal of Trauma 2004;**56**:1123-6.

5.1: Summary

Background

Endotracheal intubation remains the gold standard for trauma airway management. Rapid sequence intubation (RSI) has traditionally been performed by anaesthesiologists but increasingly, emergency physicians are also undertaking RSI. We aimed to compare success and complication rates for trauma intubations for the two specialties.

Methods

Two year, prospective multi-centre descriptive study of trauma RSI in seven Scottish urban emergency departments.

Results

439 trauma patients were identified, including 233 RSIs. Patients intubated by emergency physicians had a higher median ISS ($p < 0.001$) and lower median RTS ($p < 0.001$) compared to anaesthesiologists. For RSI, anaesthesiologists had more grade I & II views at laryngoscopy ($p = 0.051$) and more successful first attempt intubations ($p = 0.034$) but there was no difference in the number of patients suffering complications (emergency physicians 10.0%, anaesthesiologists 10.6%).

Conclusion

There is no significant difference in complication rates for trauma RSI between emergency physicians and anaesthesiologists in Scottish urban centres. A collaborative approach to the critical trauma airway is vital. Emergency physicians should consult with senior anaesthesiologists prior to RSI when intubation is predicted to be difficult.

Keywords

Airway, rapid sequence intubation, trauma, emergency medicine, anaesthesiology, complications.

5.2: Introduction

Endotracheal intubation is regarded as the gold standard for airway protection in the trauma patient (Walls 1996; Walls 1998). Traditionally, this was accomplished by anaesthesiologists [known as anaesthetists in the United Kingdom (UK)] who were called to the emergency department when required (Nolan and Clancy 2002). The development of the specialty of emergency medicine has led to some institutions in the United States (US) involving emergency physicians in airway care for trauma patients (Sakles et al, 1998; Omert et al, 2001; Bushra et al 2002). Indeed, in some hospitals, clinical responsibility for the trauma airway has shifted to emergency physicians, with anaesthesiologists available for difficult intubations (Omert et al, 2001; Bushra et al 2002).

Emergency medicine in the UK has developed since the 1970s and, in parallel with the US, some centres have developed airway care systems which involve emergency physician performed intubations (McBrien et al, 1992; Walker and Brenchley 2000; Graham et al 2003). Several US studies (Sakles et al, 1998; Tayal et al, 1999; Omert et al, 2001; Bushra et al 2002; Marvez-Valls et al, 2002) and similar studies from other countries (Dufour et al 1995; Tam and Lau 2001; Butler et al 2001) have demonstrated the safety and efficacy of emergency physician airway care, with an emphasis on rapid sequence intubation (RSI) (Walls 2000).

In Scotland, emergency physicians perform a proportion of emergency intubations in many emergency departments. The remaining intubations are performed by an anaesthesiologist or critical care physician. In the UK at present, there is an ongoing debate about the future direction of airway care in the emergency department (Nolan and Clancy 2002; Lockey and Black 2002), with some indicating a preference for an anaesthesiology based service and others advocating an emergency physician based system. There is little evidence to inform this debate for trauma patients in the UK (Butler et al 2001).

The aim of this study, therefore, was to describe the current practice of emergency physicians and anaesthesiologists with respect to the intubation of trauma patients in the emergency departments of Scottish teaching hospitals, with an emphasis on success rates, laryngoscopic views and complications.

5.3: Methods

5.3.1: Definitions

RSI was strictly defined as the administration of a potent intravenous sedative or anaesthetic agent (including thiopentone, etomidate, propofol and ketamine with or without adjunctive opioids such as fentanyl or alfentanil), immediately followed by the administration of an intravenous neuromuscular blocking agent, usually suxamethonium, to facilitate emergency endotracheal intubation (Walls 2000).

A consultant was defined as a fully trained specialist in their specialty. A specialist registrar is a senior trainee in their respective speciality, equivalent to a senior resident. A senior house officer is a doctor in training, usually with one or two years of postgraduate experience, not necessarily all in their current specialty. A staff grade doctor is a non-consultant career grade doctor, often with several years experience in their respective specialty. A senior doctor was defined as a consultant, specialist registrar or staff grade.

An intubation attempt was defined as the placing of the laryngoscope blade into the mouth, regardless of whether or not this was followed by the passage of an endotracheal tube.

5.3.2: Scottish Trauma Audit Group

The Scottish Trauma Audit Group (STAG) prospectively collects data (using TRISS methodology [Beard et al 2000]) on 98% of all trauma patients in Scotland who are admitted for at least three days or who die as a result of their

injuries. In addition to physiological data, information on emergency intubations in the emergency department is also collected.

5.3.3: Conduct of study

This was a multicentre, prospective observational study of emergency RSI for trauma patients in the emergency departments of seven Scottish urban teaching hospitals (Graham et al 2003). Data collection was performed using two independent methods. Firstly, all patients (trauma and non-trauma) on whom emergency endotracheal intubation was attempted, with or without drugs, were entered into the study. Information was collected on age, sex, reason for intubation, grade and specialty of intubating personnel, physiological status pre- and post-intubation, drugs administered, grade of laryngoscopy (Cormack and Lehane 1984) and complications encountered. The data form was completed immediately after the intubation by the intubating personnel and emergency department staff (Graham et al 2003).

There was no attempt made to change intubation practices during the course of the study. Therefore, emergency departments were free to decide which clinician (emergency physician or anaesthesiologist) was the most appropriate to deal with the patient requiring an emergency airway procedure. Following a failed intubation attempt by either specialty, further attempts as appropriate were made by the specialist who was judged most likely to succeed. Therefore a failed emergency physician attempt could be followed by another emergency physician or an anaesthesiology attempt, and a failed anaesthesiology attempt could be followed by another anaesthesiology attempt or an emergency physician attempt.

In some cases the form was not completed at the time of the intubation, usually due to critical clinical pressures at the time of performing the procedure. In these cases, the missed intubation was identified by regular examination of the resuscitation room logbooks and a data form was completed, wherever possible, from the case records and by discussing the case with the intubating staff if necessary.

The forms were checked for completeness by local investigators and then sent to the STAG Central Office in Edinburgh for data entry and subsequent analysis. Trauma patients who underwent RSI according to the above criteria were included in the study. Trauma patients who were intubated using RSI in the prehospital arena by mobile medical teams (requested on occasion by the ambulance service) were also included, but paramedic intubations in the prehospital setting were excluded as these did not involve rapid sequence intubation.

The second method of data collection was through the STAG audit process. Trauma patients are included in the audit if they are admitted to hospital for more than two days, admitted to an intensive care unit, transferred to a neurosurgical unit or the national spinal injuries unit, or if they die after admission. Certain patients are excluded, namely patients over 65 years of age with isolated fractures of the pubic rami or femoral neck, children under 13 years of age and patients sustaining burns, smoke inhalation or hanging.

A STAG form is completed prospectively by the emergency department nurses at the time of admission and includes basic identification data and physiological data on arrival. The STAG data collection form was specifically altered to include a field which indicated that endotracheal intubation had been performed in the resuscitation area. This was used to ensure that all eligible patients were identified and included in the study. STAG local coordinators check all the admission details and follow the patients through to death or hospital discharge.

Data were collected for a two year period starting on 11 January 1999. Both the intubation form data and STAG form data were entered on to SPSS v9.0 (Statistical Package for Social Sciences, v9.0, Chicago, IL 60611, US) and a further manual matching procedure was used to improve the number of matches between the datasets.

5.3.4: Statistical analyses

Mann Whitney U tests were used to compare continuous non-parametric data (ISS, RTS, time to definitive airway) and chi square tests were used to compare categorical data.

Statistical significance was defined as $p < 0.05$, but exact values are given in the results. As much data as possible was collected on all patients, although not all data fields were completed on all patients. This is reflected by different numbers of patients in the results.

5.4: Results

The study ran as planned for two calendar years. 1 713 patients were identified who had been subjected to an intubation attempt in the resuscitation room, of whom 439 were trauma patients. 309 (70.4%) patients were successfully matched with STAG forms. The intubating specialty was identifiable in 396 (90.2%) patients.

Table B5.4.1 details the patient characteristics of the two intubating specialty groups, namely emergency medicine and anaesthesiology.

Table B5.4.1

Patient characteristics of the two intubating specialties (n=396)

	Emergency Physician	Anaesthesiology	p
Number (%) of patients	152 (38.4%)	242 (61.1%)	-
Median age	36.5 years	37 years	0.73 [^]
Number (%) of males	127 (83.6%)	209 (86.4%)	0.44*
Median ISS	27	24	<0.001 [^]
Median RTS	4.9	5.97	<0.001 [^]
Head AIS ≥ 3	113 (74.3%)	192 (78.9%)	0.35*
Spinal injury	36 (23.7%)	45 (18.6%)	0.28*
Mandible fracture	9 (5.9%)	10 (4.1%)	0.57*
Le Fort II fracture	0	7 (2.9%)	0.085*
Le Fort III fracture	1 (0.7%)	2 (0.8%)	1.0*

In addition, one patient had an emergency tracheostomy under local anaesthesia by an ear, nose and throat surgeon and one patient was intubated by a paramedic under medical supervision.

ISS: Injury severity score

RTS: Revised trauma score

AIS: Abbreviated injury score

*: Chi squared test

[^]: Mann Whitney U test

The data show that the group of trauma patients on whom emergency physicians are performing RSI are more severely injured ($p < 0.001$, Mann Whitney U test) and have greater physiological compromise ($p < 0.001$, Mann Whitney U test) than those intubated by anaesthesiologists.

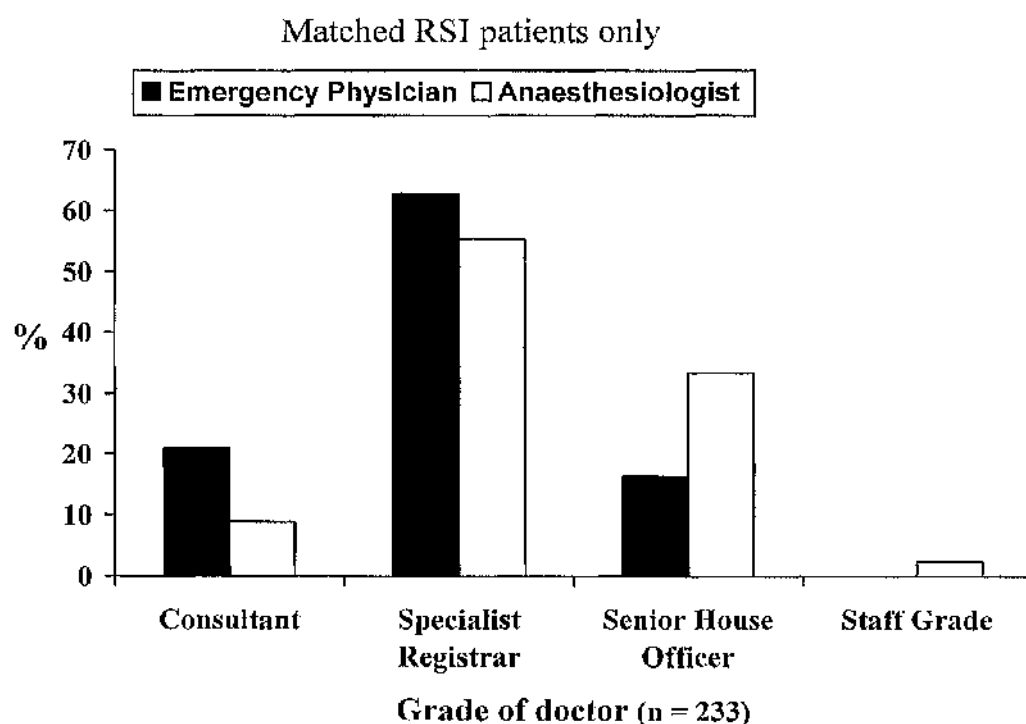
There were no significant differences in the rates of significant head injury, spinal injury, or maxillofacial injuries that may complicate airway control between the two groups. The two groups were comparable with respect to age and sex.

The rest of this analysis focuses on those trauma patients who were intubated using an RSI technique as defined previously and on whom data is available from both the intubation form and the STAG form (matched RSI patients, $n=233$).

Figure B5.4.1 shows the grade of intubating doctor for the two specialties. These data show that the intubating doctor is of a more senior grade in the emergency physician group compared to the anaesthesiology group (80.9% versus 65%, $p=0.003$, Chi square test).

Figure B5.4.1

Grade of doctor by intubating specialty



More senior doctors in the emergency physician group compared to the anaesthesiology group (80.9% versus 65%, $p = 0.003$).

Table B5.4.2 details the ease of laryngoscopy (as measured using the Cormack-Lehane grading system [Cormack and Lehane 1984]), first pass success rates for intubation and number of patients sustaining complications, all data relating to the matched RSI patients, $n=233$. Complications are detailed in Table B5.4.3.

Table B5.4.2

Matched trauma RSI results

	n	Emergency Physician	Anaesthesiology	p
Grade I & II laryngoscopy	207 [^]	89/103 (86.4%)	99/104 (95.2%)	0.051*
Successful intubation on first attempt	233	84/110 (76.4%)	108/123 (87.8%)	0.034*
Number of patients with any complication	233	11/110 (10.0%)	13/123 (10.6%)	1.0*

*: Chi squared test

[^]: 26 patients did not have grade of laryngoscopy data recorded at the time of intubation

Table B5.4.3

Complications by intubating specialty

Complication	Emergency Physician	Anaesthesiology
Oesophageal intubation	7	4
Endobronchial intubation	1	1
Aspiration	1	2
Vomit/regurgitation	1	2
Critical desaturation	2	4
Cardiac arrest	0	0
Hypotensive episode	1	3

All oesophageal intubations were immediately recognised and the trachea was intubated subsequently on each occasion.

There was a 100% success rate for up to three attempts at intubation in this study. Only seven patients (six by emergency physicians, one by anaesthesiology) required three attempts for successful intubation. Overall, the median time from entering the emergency department to achieving a definitive airway was 12 minutes for the emergency physician group compared to 33 minutes for the anaesthesiology group ($p < 0.001$, Mann Whitney U test).

However, when only urgent intubations are considered (those intubated within 15 minutes of arrival in the emergency department), the median times were not statistically different (medians: emergency physicians 6 minutes ($n=80$), anaesthesiologists 7 minutes ($n=26$), $p=0.055$, Mann Whitney U test).

5.5: Discussion

This study shows that emergency physicians undertake RSI on trauma patients with a higher median ISS and lower median RTS as compared to anaesthesiologists.

This suggests that emergency physicians are performing RSI on trauma patients who are more severely injured and have greater physiological compromise than those intubated by anaesthesiologists. This may also explain the observed shorter median time to intubation for patients intubated by emergency physicians given the higher likelihood for the immediate need to secure the airway in critically injured patients.

A significant proportion of patients in the anaesthesiology group were intubated semi-electively for transfer to regional neurosurgical units which prolongs the anaesthesiology times overall. However, for urgent intubations (those performed within 15 minutes of arrival in the emergency department), the median times to intubation for each specialty are not statistically significantly different.

This suggests that whatever system an emergency department has in place for critical management of the emergency airway (either emergency physicians or anaesthesiologists), both specialties can effectively deal with the early management of the threatened airway in the trauma patient.

In our study, anaesthesiologists obtained better views at laryngoscopy and had a higher initial success rate for intubation when compared to emergency physicians. Anaesthesiologists may have superior laryngoscopy skills given their extensive experience of intubation and this may explain the higher initial success rate.

The poorer laryngoscopy views observed in the emergency physician group suggest that further exposure to this skill may be required in emergency physician training. It is likely, although not certain, that this would lead to higher initial intubation attempt success rates.

Anaesthesiologists undoubtedly have more exposure to airway management as part of their training and ongoing daily work and this may be a factor in the observed difference in laryngoscopy skills. However, the emergency physician

group were more seriously injured and more physiologically compromised and the urgency of the requirement for airway control may have contributed to the observed difficulties in laryngoscopic visualisation.

The lack of an observed difference in complication rates between the two groups shows that appropriately trained and experienced emergency physicians in urban centres in Scotland are capable of performing RSI on trauma patients in the emergency department with a similar high level of patient safety compared to anaesthesiologists.

It is possible that, due to appropriate triaging of predictably difficult airways, anaesthesiologists are requested to attempt intubation on more difficult trauma patients and this could influence the results noted. This collaborative, "team approach" to the trauma patient requiring airway control is an ideal approach but may not always be possible due to lack of availability of senior anaesthesiology staff.

However, if an intubation is predicted to be difficult, it may be in the best interests of the patient that a senior anaesthesiologist be consulted prior to any intubation attempt on a trauma patient by the emergency physician.

Further large, prospective studies are required to clarify the factors influencing airway management in the emergency department, including the optimum personnel and system for effective emergency airway assessment and control.

6: Scottish urban rural trauma outcome study

McGuffie A C, **Graham C A**, Beard D, Kerr G W, Wilkie S C, Fitzpatrick M O, Henry J, Parke T R J.
Scottish urban versus rural trauma outcome study.
Journal of Trauma 2005;**59**:632-638.

6.1: Summary

Background

Outcome following trauma and healthcare access are important components of healthcare planning. Resources are limited and quality information is required. We set the objective of comparing the outcomes for patients suffering significant trauma in urban and rural environments in Scotland

Method

The study was designed as a two year prospective observational study set in the West of Scotland with a population 2.58 million persons. Primary outcome measures were defined as the total number of inpatient days, total number of intensive care unit days and mortality. The participants were patients suffering moderate (ISS 9-15) and major (ISS >15) trauma within the region. The statistical analysis consisted of Chi square test for categorical data and Mann Whitney U test for comparison of medians.

Results

3 962 urban (85%) and 674 rural patients (15%). Urban patients older (50 v 46 years, $p=0.02$), more males (62% v 57%, $p=0.02$) and more penetrating trauma (9.9% v 1.9%, $p<0.001$). All prehospital times significantly longer for rural

patients ($p<0.001$), more air ambulance transfers ($p<0.001$) and a greater paramedic presence ($p<0.001$).

Excluding neurosurgical and spinal injuries transfers, higher proportion of transfers in the rural major trauma group ($p=0.002$). More serious head injuries in the urban group ($p=0.04$) and a higher proportion of urban patients with head injuries transferred to the regional neurosurgical unit ($p=0.037$).

There were no differences in length of total inpatient stay (median 8 days, $p=0.7$), total length of stay in the intensive care unit (median two days, $p=0.4$) or mortality (324 deaths, moderate trauma, $p=0.13$; major trauma, $p=0.8$).

Conclusion

Long prehospital times in the rural environment were not associated with differences in mortality or length of stay in moderately and severely injured patients in the West of Scotland. This may lend support to a policy of rationalisation of trauma services in Scotland.

Keywords

Urban; rural; trauma; outcome; Scotland.

6.2: Introduction

Scotland is made up of the densely populated, mostly urban, central belt which is sandwiched between the less densely populated areas of southern Scotland,

and the sparsely populated Highlands. To the west, there are outlying islands, which are also sparsely populated and have few health care facilities.

Rurality is a difficult concept to define (Hope et al 2000). Perhaps the most commonly used definition in Scotland is the Randall definition, which uses a cut off of areas with less than one person per hectare (Scottish Parliament, 1999). A common feature, however, is that people living in rural Scotland have longer distances to travel to hospital when they are injured or ill compared to urban dwellers.

Trauma remains a common cause of death in the UK (Anderson et al, 1988) and worldwide (Murray and Lopez 1997; Krug et al 2000; MacKenzie 2000) and causes untold disability for its victims. Several authors have suggested that the pattern of trauma is different for rural compared to urban populations and that the distances involved, and consequent time delays, may have a significant effect on trauma mortality for rural patients (Baker et al 1987; Esposito et al 1995; Rogers et al 1999).

The current practice of the Scottish Ambulance Service is to take trauma patients to the nearest hospital with an emergency department (ED), regardless of size or specialty availability. Subsequent transfer is dictated by clinical need and transport is provided by the Scottish Ambulance Service, either by road or by air.

Occasionally trauma patients from a more remote location are transported to an urban hospital directly from the scene by air ambulance, but this depends on the availability of the helicopter and is not subject to strict protocols.

The Scottish Trauma Audit Group (STAG) was established in 1991 to provide objective evidence of trauma outcome on both a national and individual hospital level (Beard et al 2000). Twenty six hospitals contributed to the database which contains data that have been prospectively collected on more than 51 000 trauma patients up to the end of December 2002.

The entry criteria for the STAG database are all trauma patients who die as a result of trauma or are admitted for more than two days, or are transferred to a regional or national specialist service. This includes patients who die in the ED as a result of trauma, except those declared dead within 15 minutes of arrival. Patients over the age of 65 with isolated femoral neck or pubic ramus fractures and children under the age of 13 are excluded.

Data are collected prospectively by ED medical and nursing staff with follow-up information collected on an individual hospital basis by local audit co-ordinators. STAG utilises TRISS methodology (Boyd et al 1987), a combination of two validated trauma scores, namely the physiologically based Revised Trauma Score (RTS) (Champion et al 1990) and the anatomically based Injury Severity Score (ISS) (Copes et al 1988). The RTS, ISS, patient's age and type of injury (blunt or penetrating), allow a probability of survival to be calculated for each patient.

Previous work using STAG data (Wyatt et al 1995) has shown that Scotland does not conform to the accepted trimodal distribution of trauma deaths as suggested by Trunkey (1983). This and other work done by Wyatt emphasised the importance of injury prevention in Scotland as there may be difficulties in improving early care as the trimodal distribution of death could not be identified in the Scottish trauma population.

Patients in rural Scotland have to travel greater distances to hospital following trauma compared to those who are injured in urban areas. We hypothesised that there may be a difference in mortality and length of stay between rural and urban victims of trauma. The aim of this study was to compare outcomes for patients sustaining significant trauma in an urban or a rural environment in Scotland.

6.3: Methods

The project was a multi-centre, prospective, observational study over a two year period between November 1998 and October 2000. The study population was defined as those patients eligible for entry into the STAG database who had sustained moderate trauma (defined as ISS 8-15) or major trauma (ISS 16-75) and had arrived at hospital either by self-presentation, by road ambulance or by air ambulance in the west and south-west regions of Scotland. This area is served by a regional neurosurgical centre, the Institute of Neurological Sciences at the Southern General Hospital in Glasgow, and contains an estimated population of 2.5 million people (Figure B6.3.1, Table B6.3.1).

Figure B6.3.1

Map of Scotland: approximate geographical boundaries of the area covered by the Institute of Neurological Sciences, Southern General Hospital, Glasgow

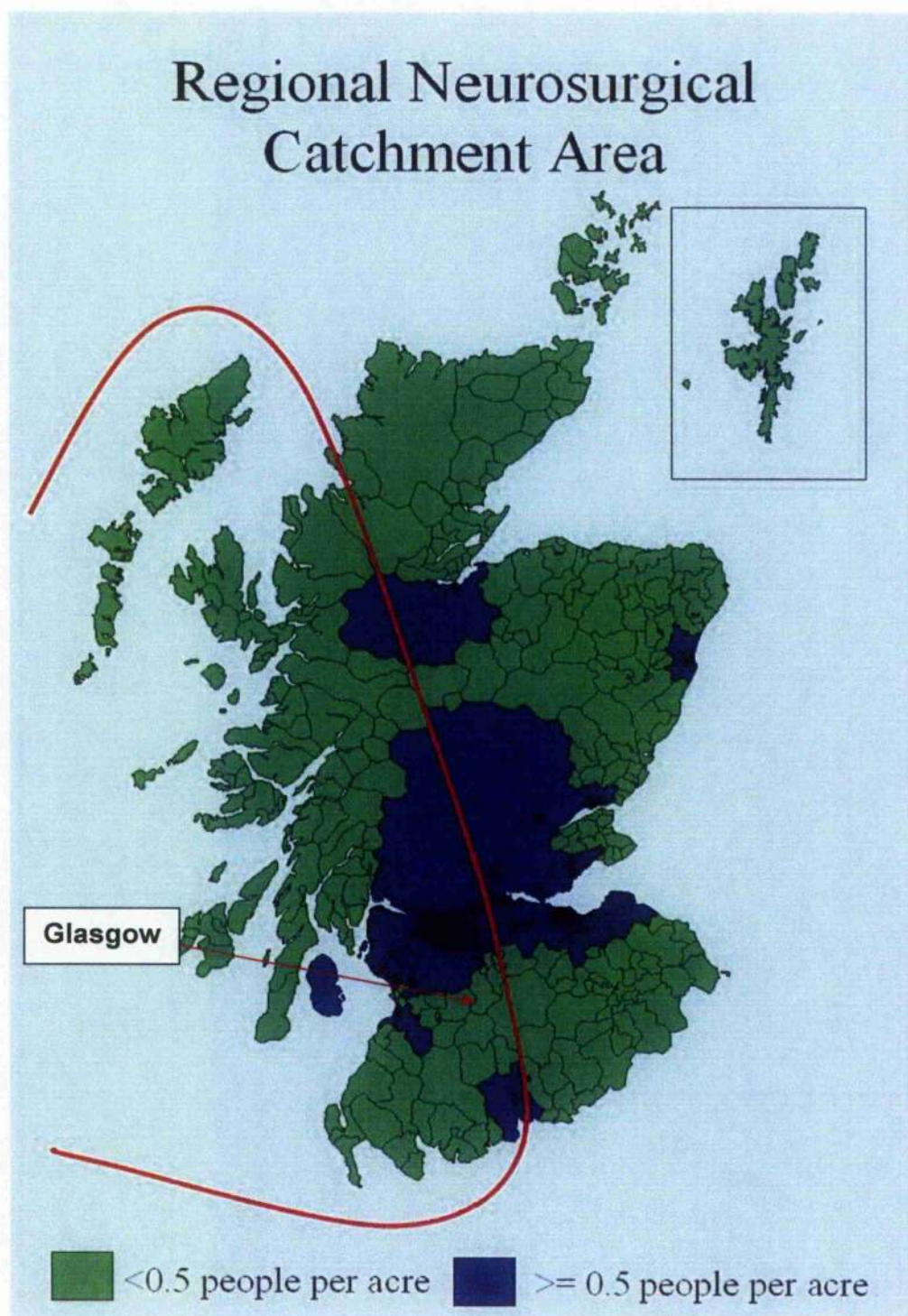


Table B6.3.1**Scottish and study populations**

	Scotland	Study population
Urban	3 625 790 (71%)	2 024 530 (79%)
Rural	1 476 010 (29%)	552 440 (21%)

It was estimated from previous STAG data that there would be approximately 2000 patients eligible for entry into the study and around 200 pre-hospital deaths per year within the study region.

As no satisfactory definition of an urban or rural population could be identified in the UK trauma literature, the Scottish Ambulance Service response time standards for population density were used to define the study groups (Table B6.3.2, Figure B6.3.1).

Table B6.3.2

Scottish Ambulance Service ORCON population banding: definitions and response time targets

			Response standards	
	Population density	Definition	50%	95%
Urban	> 3 persons per acre	high	7 minutes*	14 minutes
	> 0.5 & < 3 persons per acre	medium	8 minutes	18 minutes
Rural	< 0.5 persons per acre	sparse	8 minutes	21-24 minutes

* i.e. 50% of calls within this population definition should be attended by an ambulance crew within 7 minutes, 95% within 14 minutes, etc.

These response standards, known as ORCON (Operational Control) standards, resulted from work on emergency cover arrangements across all mainland Health Boards in Scotland (Chapman 1996). It incorporated both census and local government district data to produce population densities.

A population density of more than 0.5 persons per acre was defined as urban for the purposes of this study. These definitions are broadly comparable to the

Randall definition of rurality, which defines "rural" local authorities as those with less than one person per hectare² (2.471 acres = 1 hectare).

STAG local co-ordinators were provided with detailed coding maps of their own areas and allocated each patient a population density code of either urban or rural depending on the incident location. Data were collected in each of the fifteen main hospitals within the study region.

In addition, there is a network of community hospitals that occasionally receives trauma patients and therefore subsequent transfers into the main hospitals were also monitored and data collected on arrival at the secondary hospital. Direct transfers to the regional neurosurgical unit from community hospitals were handled in the same manner.

Data were collected prospectively and included the location and type of incident, pre-hospital times for ambulance transfers, paramedic presence, RTS on admission, ISS on discharge, transfer status, means of transfer and destination, seniority of ED doctor, response times and seniority of other specialities, destination from the ED, length of time to operation and type of operation, and grade of surgeon and anaesthetist. Probability of survival was calculated for each patient using standard UK coefficients that have been used by UKTARN and are internationally accepted.

Primary outcome measures were defined as total number of in-patient days, total number of days in the intensive care unit and mortality.

The collected data were reviewed by the investigators to check for errors in the coding of incident location and to identify any deaths during transfer from scene to first hospital or subsequent inter-hospital transfer.

In hospitals that did not have emergency department (ED) consultants in post, the presence of any consultant (surgeon, anaesthetists, orthopaedic surgeon, etc.) was taken as equivalent to the presence of a consultant in emergency medicine for the purposes of this study. A consultant provides clinical care at the same level as an attending or a staff specialist would do in North America.

6.3.1: Statistical analyses

Data were analysed using SPSS v11. Categorical data were compared using the chi square test (χ^2 test). Continuous data were compared using the Mann Whitney U test due to the non parametric distribution of the data. Significance levels were set at $p < 0.05$.

Logistic regression was used to determine whether population density had an independent effect on final outcome of the patient and on whether the patient spent time in ICU or not. Forward step-wise models were fitted to determine if population density had an independent effect on whether or not a patient was admitted to ICU and final outcome.

Other explanatory variables included age, RTS, ISS, mechanism of injury, type of injury, the presence of a paramedic at scene, initial triage area and ambulance response time, on-scene time and transfer to hospital time. Times underwent a logarithmic transformation to achieve an approximately normal

distribution. Multiple regression was used to determine whether population density had an independent effect on length of stay and length of time spent in ICU. A stepwise method was adopted and explanatory variables were as above.

6.4: Results

Prospective data collection extended over a 24 month period from November 1998 to October 2000. A total of 4 636 trauma patients fulfilled the entry criteria and had a population density code allocated. A further 105 patients were excluded as it was impossible to allocate a population density code for the location of the incident.

During the study period there were 656 patients who did not arrive by ambulance although it was subsequently possible to identify the location where the injury had occurred. Of these patients 580 individuals were injured in an urban environment and 76 were injured in a rural environment. As they had not arrived by ambulance, detailed pre-hospital times were not available.

It was considered valid to include these patients in the outcome analyses in view of the fact that a definite incident location could be identified although they were not included in the analysis of transport times or paramedic presence.

The urban patient population constituted a group of 3 962 patients (85%) and the rural group 674 patients (15%). Urban patients were older (median 50 years, rural median 46 years, $p=0.02$, Mann Whitney). There were significantly

more males in the urban group (62% v 57%) and more females in the rural group (43% v 38%, $p=0.02$, Mann Whitney). There were no differences between the groups in terms of ISS ($p=0.84$, Mann Whitney) or RTS ($p=0.22$, Mann Whitney).

There were fewer penetrating trauma victims in the rural group (1.9% rural v 9.9% urban, $p<0.001$, χ^2 test). Mechanisms of injury are shown in Table B6.4.1. In essence, urban patients had an excess of assaults and low falls, whereas rural patients were the victims of road traffic accidents, sports injuries and other injuries (including industrial and farming injuries).

Table 6.4.1

Distribution of trauma patients between urban and rural groups

	Urban	Rural	p
Road traffic accident	19.2%	33.8%	<0.001
Assault	16.0%	4.0%	<0.001
High fall (> 2 metres)	8.8%	10.2%	0.24
Low fall (< 2 metres)	46.8%	37.8%	<0.001
Sport injuries	2.9%	5.6%	<0.001
Other injuries	6.3%	8.5%	0.047
Total	3962	674	

The data were then analysed in the pre-hospital, ED and post ED phases.

6.4.1: Pre-hospital phase

All components of the pre-hospital times were significantly longer for the rural group ($p < 0.001$, Mann-Whitney) as illustrated in Figure B6.4.1.

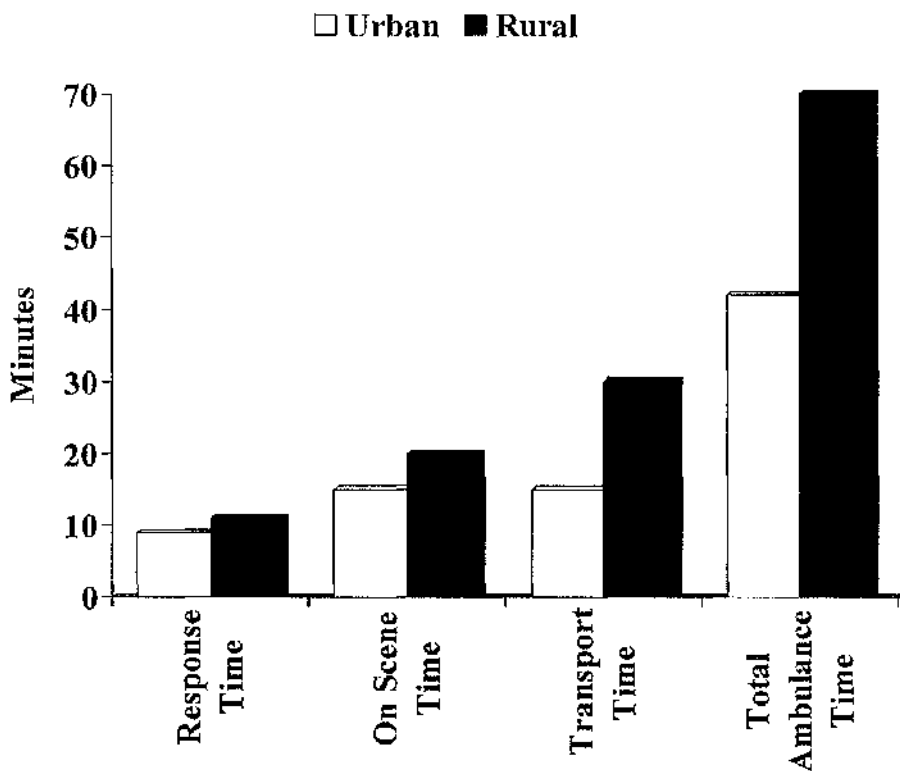
A significantly greater proportion of the rural patients arrived at the ED by air ambulance (13.2% v 0.8%, $p < 0.001$, χ^2 test).

There was a greater paramedic presence in the rural group in both the moderate and major trauma groups (ISS 9-15: 69% v 51%, $p < 0.001$, χ^2 test; ISS 16-75: 88% v 55%, $p < 0.001$, χ^2 test).

No patients were found to have died during the primary transfer (from scene to hospital) or during subsequent interhospital transfers.

Figure B6.4.1

Pre-hospital times (all patients)



Response time: Time from call for ambulance until ambulance arrives on scene

On scene time: Time from arrival on scene to departure from scene

Transport time: Time from departure from scene to arrival at the ED

Total ambulance time: Total of response time, on scene time and transport time

6.4.2: Emergency department phase

Both the urban and rural groups were matched in terms of ISS with 2 974 (75%) patients injured in an urban environment suffering moderate trauma and 988 (25%) patients suffering major trauma compared with 509 (75%) of patients injured in a rural environment suffering moderate trauma and 165 (25%) suffering major trauma.

In the moderate trauma group (ISS 9-15), a higher proportion of rural patients were triaged into the resuscitation room (41% rural v 35% urban, $p=0.01$, χ^2 test). This pattern was repeated in the major trauma group (ISS 16-75), with 92% of rural patients being triaged into the resuscitation room compared to 73% of urban patients ($p<0.001$, χ^2 test).

In the rural group, 46% of patients with a normal RTS were triaged into the resuscitation room, compared with 36% of the urban group with a normal RTS ($p<0.001$, χ^2 test).

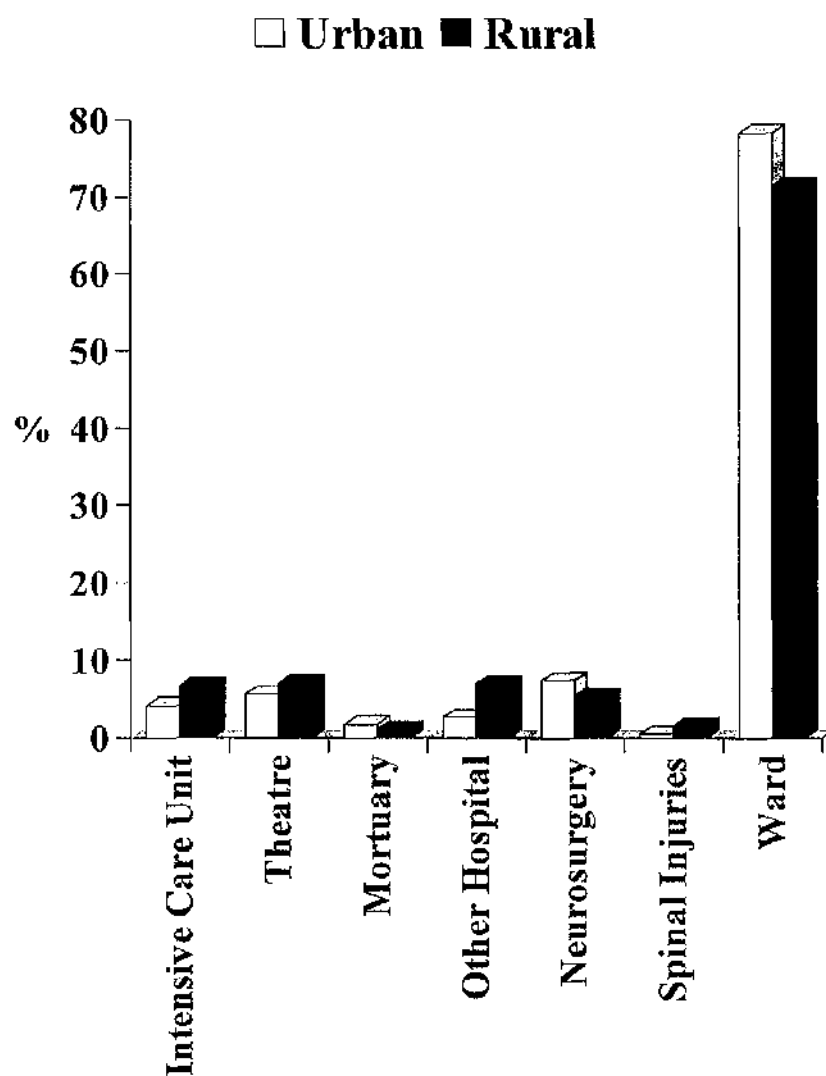
There were no differences in ED consultant presence for urban and rural groups (20% urban v 21% rural, $p=0.6$, χ^2 test). There was no difference in the total amount of time spent in the ED for the two groups (median 135 minutes for urban patients, median 138 minutes for rural patients, $p=0.9$, Mann Whitney).

6.4.3: Post ED phase

The destination of patients from the ED is shown in Figure B6.4.3.

Figure B6.4.3

Destination from emergency department



The category 'other hospital' indicates a transfer to another health care facility based on patient needs and may have been for cardiothoracic services, orthopaedics, critical care or other specialist services outwith the capability of the original centre.

Within the major trauma group (ISS 16-75), there were more secondary transfers to other hospitals (excluding neurosurgery and spinal injuries) amongst rural patients (6.7% v 2.1%, $p=0.002$, χ^2 test) but no difference in direct neurosurgical transfers from the ED (urban 24%, rural 18%, $p=0.08$, χ^2 test). Therefore more rural patients were transferred for reasons other than the need for neurosurgery.

However, amongst major trauma patients, there were more transfers to the neurosurgical unit (early and late) in the urban group compared to the rural group (40% v 27%, $p=0.002$, χ^2 test). More major trauma patients were transferred to the national spinal injuries unit in the rural group (4.2% v 0.6%, $p<0.001$, χ^2 test).

There was a higher proportion of significant head injuries (defined as abbreviated injury score (head) ≥ 3) in the urban group compared to the rural group (24% v 21%, $p=0.04$, χ^2 test). A greater proportion of urban patients with head injuries were transferred to the regional neurosurgical unit (49% v 40%, $p=0.037$, χ^2 test).

A higher proportion of rural patients requiring surgery were operated on by a consultant surgeon (70% v 57%, $p<0.001$, χ^2 test). Similarly, a higher proportion

of rural patients were anaesthetised by a consultant anaesthetist (54% v 46%, $p=0.005$, χ^2 test) compared to the urban group.

6.4.4: Primary outcome measures

A higher proportion of rural patients were admitted to an intensive care unit (15% v 10%, $p<0.001$, χ^2 test). However, logistic regression analysis did not indicate that population density had an effect on determining ICU admission (p to enter = 0.426). Transport time was included in the model and given the association between transport time and population density, the interaction between population density and transport time was considered as an explanatory variable. This interaction was not added to the model ($p = 0.232$).

There were no differences between urban and rural patients in terms of length of intensive care stay (median two days, $p=0.4$, Mann Whitney) or total in-patient stay (median eight days, $p=0.7$, Mann Whitney). Population density was not considered a significant factor when total length of stay was modelled using multiple regression analysis. Transport time (scene to hospital) was considered a significant factor in the model with the best fit. However, adjusted r^2 for this model was very low (0.081) indicating that the model accounted for very little of the variation in length of stay.

None of the pre-hospital times or population density were selected as factors in predicting length of stay in ICU using multiple linear regression. Injury severity score was the only factor selected but again the adjusted r^2 for this model was very low (0.057).

In total 324 patients died, which represented 7.0% of the study population.

There were no differences in mortality for the moderately injured group (ISS 9-15, urban 2.1% v rural 1.0%, $p=0.13$, χ^2 test) or the major trauma group (ISS 16-75, urban 22.5% v rural 21.2%, $p=0.8$, χ^2 test).

6.5: Discussion

A rural population can be described in terms of area size, population density, geography, lifestyle factors, values or behavioural factors. The Committee on Trauma of the American College of Surgeons defines rural as 'an area where geography, population density, weather, distance or availability of professional or institutional resources combine to isolate the trauma victim in an environment where access to definitive care is limited' (American College of Surgeons 1999).

Prior to this study, no UK definition of "rural" with respect to trauma was identified. The definition of rural for this study was considered robust in that it utilised population density and remoteness in terms of ambulance response times. It was therefore likely to be the case that the pre-hospital times for this group would be longer thus introducing a possible delay to definitive care. The limitation of such a definition is the fact that there may be a relatively densely populated or urbanised area with more advanced trauma care within a more sparsely populated area and vice versa.

However, this definition, by focussing on the location of the traumatic incident rather than the 'rurality' of the healthcare facility, should minimise any systematic bias that may result. Given that all the hospitals in the study

admitted patients who were injured in both rural and urban environments, the study design addresses the issue of access to trauma care in this region. This definition resulted in city hospitals admitting a high proportion of patients injured in an urban environment.

In view of the fact that district hospitals tend to be located in densely populated pockets within rural areas, the majority of patients admitted to district hospitals had been injured in an urban environment. However, a greater proportion of patients injured in a rural environment are admitted to these establishments. Tertiary care is exclusively available within city hospitals.

Within the west and south-west region of Scotland, patients sustaining significant trauma in either an urban or rural setting were well matched in terms of anatomical injuries (ISS). All transfer times to hospital were longer for the rural group. Physiological derangement (RTS) at presentation was not significantly different between the two groups. No deaths in transit were identified in either group which is consistent with Wyatt et al's findings of the timing of trauma deaths in Scotland (Wyatt et al 1995).

This finding may lend support to the accumulating evidence that there is an absence of a trimodal distribution of death in Scotland.

There was a significantly greater paramedic presence for patients injured in rural settings, which may reflect prioritised tasking of ambulance resources or the fact that there is a higher proportion of paramedic staffed ambulances in rural areas (Rainer et al 1997).

A greater proportion of rural patients were transported to hospital by air ambulance. This may reflect subjectively targeted dispatch of air ambulance resources to rural incidents. In this region, helicopter air ambulance deployment is not subject to strict protocols.

However, the rationale behind this could be to minimise prehospital times or to provide access to remote locations which are inaccessible by road. The appropriateness of helicopter transport is dependent on factors such as availability, patient volumes, injury severity, weather and traffic patterns and ground transport availability.

Although this study observed routine transport practice in the region, the effect of air ambulance transport on the outcome of rural trauma patients is unknown. It is possible that air transport introduced bias into the results, although given the small number of patients transported by air (30 patients in the urban group, 89 patients in the rural group), this is unlikely to lead to a systematic error.

Trauma patients in Scotland are triaged either into the resuscitation room or the general emergency department based on the perceived severity of the injuries as assessed by the ambulance crews or the triage nurse. Despite comparable injury severity, a higher proportion of rural patients were triaged to the resuscitation room on arrival. This may be the result of prolonged prehospital times allowing EDs to plan ahead. Alternatively, it could be due to the higher proportion of paramedics in the rural group who are more likely to triage trauma

patients to the resuscitation room than ambulance technicians (Rainer et al 1997).

There were equal proportions of consultant presence in the ED for patients from both the rural and urban groups. As might be expected, more rural patients were transferred to urban tertiary referral centres for definitive care.

The excess of rural transfers overall does not appear to be associated with a lack of diagnostic imaging capabilities (e.g. computed tomography scanning) at the rural hospital, as evidenced by the similar early transfer rates from the ED to the regional neurosurgical centre.

More patients injured in a rural environment were transferred to the national spinal injuries unit. This is likely to be due to differing mechanisms of injury, particularly the excess of road traffic accidents and sports injuries in the rural group. The excess of severe ($\text{AIS} \geq 3$) head injuries seen in the urban group is likely to reflect the pattern of assaults seen in urban environments.

Of those requiring surgery, patients injured in a rural environment were more likely to be treated by consultant surgeons and consultant anaesthetists.

Patients who do not have their care delivered by a consultant are treated by more junior doctors. These individuals are either in a training position or a service position. Training doctors are either Senior House Officers (junior trainees) or Specialist Registrars (specialist trainee level) and service doctors consist of Staff Grade doctors and Associate Specialists.

The overall finding may be due to different working practices in hospitals which received a higher proportion of rural patients. Although the treating doctor may have discussed the case with a consultant it was the most senior anaesthetist and surgeon who were present in the operating theatre that were recorded as providing care.

Despite significantly longer prehospital times and with comparable patient populations, there was no significant difference in the primary outcome measures between urban and rural patients. This may have a significant bearing on the planning and provision of UK trauma care.

Multiple pressures are currently being brought to bear on the provision of emergency trauma care within the UK particularly the availability of fully trained senior staff to provide primary resuscitation and surgical and intensive care management in more peripheral units. This has been compounded by an effective reduction of the availability of more junior doctors to support the service secondary to legislation to reduce permitted hours of work.

Centralisation of trauma services following a model more akin to North American trauma service provision is currently on both the professional and the political agenda. The perceived hazards of long distances and prolonged prehospital times have not been borne out by this study, which lends support to a policy of rationalisation with respect to trauma services in Scotland. Despite this, the counter-argument, to continue with non-centralised trauma care, does not appear to be associated with excess mortality according to the results seen in this study.

One potential criticism of this work is the real possibility of a type II error, namely that the number of deaths seen in each group is too small to allow any statistically meaningful differences to be found without very large numbers of patients.

Given the fact that this study included nearly half of the potentially injured population of Scotland, and the prolonged time period over which it was undertaken, it is unlikely that any future study will be able to give a definitive answer to this question in the Scottish context.

7: Investigator contributions to Section B

For the studies described in Section B, I was principal investigator and writer for the studies described in Sections B1, B2, and B5 and completed 75-90% of each individual study. For each study, I initiated the studies, developed the concepts and study methods, helped to gather and analyse the data, interpreted the data, and drafted and edited the final report (paper) for the study.

My co-investigators and co-authors contributed to data collection and analysis, and made important contributions to data interpretation and editing of the final reports for the studies. Specifically, Diana Beard and Rik Smith of the Scottish Trauma Audit Group helped greatly to locate, collect and analyse data for these three studies, and I acknowledge their significant contribution.

Specifically, for Section B3, I had the original idea, designed the study, collected data, drafted and edited the manuscript; Gary Wares assisted in study design, data collection and manuscript editing; and Phil Munro assisted in study design, data collection and manuscript editing.

For Section B4, I would like to thank all the nursing and medical staff in the Emergency Department at Crosshouse Hospital for their cooperation and hard work which allowed the study to be done. I also thank Advanced Data Services Ltd. (Glasgow) for help with data entry and analysis. In addition, the Procurator Fiscal in Kilmarnock kindly gave their assistance with this study.

For the study described in Section B6, I was responsible for around 30% of the study design, analysis and writing up of the paper. Crawford McGuffie was responsible for the original idea, preparation and development of the protocol, data collection, data cleaning, analysis of data, drafting and editing the paper, and overall coordination of the study. I was responsible for the development of the protocol, data collection, analysis of data, drafting and editing the paper. Diana Beard developed the protocol, designed the data form, performed data collection, post-mortem data collection, data cleaning, analysis of data, and editing of the paper.

Jenny Henry also developed the protocol and performed statistical data analysis and interpretation, and edited the paper. Michael Fitzpatrick was involved in development of the protocol, data collection at the regional neurosurgical centre, analysis of data, and editing of the paper. Stewart Wilkie was involved in the development of the protocol, data collection, post-mortem data collection, analysis of data, and editing of the paper. Gary Kerr assisted with development of the protocol, data collection, data cleaning, analysis of data, and editing of the paper. Tim Parke assisted with development of the protocol, analysis of data, editing of the paper, and was the project supervisor.

Section C: Conclusion and the future

1: Conclusion

This thesis has examined aspects of trauma systems, trauma outcome and progress in trauma management in Scotland over the last decade. Trauma remains a major public health issue and requires continuing clinical and public health input. The predicted global increase in the incidence of trauma means that countries that have effective strategies for injury prevention and control and for measuring outcome in both mortality and morbidity terms will be able to help less advanced nations improve their services.

This body of work adds to the literature on major trauma outcomes in several domains. Firstly, outcome following trauma in Scotland is poorly understood, partially due to ethical and practical difficulties of accessing patients and information. This could be tackled to a significant degree by utilising a registry based design for major trauma follow up throughout Scotland. The practical difficulties of keeping track of mobile individuals will remain challenging, but consent, access and data protection issues may be minimised by this approach.

Secondly, this work can inform to an extent the tools that should be used for future work. Such tools must be user and patient friendly, and it must be possible for any trained health care professional (not just a doctor) to use them. The SF36 is suitable, well tested and useful. The AMAIS is not suitable given its complexity, and the FIM has significant ceiling effects which minimise its usefulness for long term follow up. The CIQ is promising but requires further larger scale study to identify its role within the follow up system. Impairment itself, along with ability, may be relatively unimportant in the global assessment

strategy, whereas participation and work status along with overall health status may be much more important and relevant to the individual, to health care systems and to society.

Thirdly, the data in this work suggests that despite survivors having more impairment than controls, and poorer health status, but they have little difference in employment status. This confirms other US and UK studies that suggest that health status and impairment have a complex relationship with return to work status, and raises the possibility that further clarification of that relationship may potentially lead to increases in the proportion of patients returning to work after trauma.

Other work presented in this thesis suggest that long prehospital times in the rural environment do not impact upon mortality compared to shorter times to hospital care in the urban environment. Rationalisation of trauma services and concentration of trauma workload in fewer centres may not lead to poorer prehospital outcomes for trauma patients. What this study does not do though, is examine the morbidity of survivors, which is a more interesting and relevant question which currently remains unanswered.

Two other studies in the thesis deal with aspects of cervical spine care, with data showing that spinal cord injury due to penetrating trauma is rare in Scotland, and fully conscious patients who sustain isolated penetrating trauma do not require cervical spine immobilisation. This may reduce times to hospital care for this frequently critically injured population and may have an impact on

survival, especially given the relatively high number of penetrating trauma patients seen in the West of Scotland.

On the contrary, in blunt injury, cervical spine injury was shown to have no relationship with the ED GCS, although patients with a GCS of 3 are more likely to have a cervical spine injury following blunt trauma. The crucial importance of spinal immobilisation in the field for blunt trauma patients is demonstrated by the incidence of 5.3% for cervical spine injury after blunt head injury in Scotland.

Trauma intubation was shown in a landmark national study to be equally efficacious in the hands of emergency physicians and anaesthetists in Scotland.

The study of a small population of critically injured patients in Scotland suggests that contrary to previous beliefs, a small number of critically injured patients who are intubated in the emergency department may survive with aggressive resuscitation efforts.

Children are a unique subset of the trauma population, and prevention efforts can be variable. This prospective study suggests that focusing on school incidents, use of cycle helmets and increasing adult supervision particularly in the 5-13 year age group may have some impact. Further evaluation is clearly warranted but specific provision of research assistants for data collection is mandatory to improve the quality of data collection.

2: The future

Trauma is not going to disappear overnight, and therefore a strategy for trauma research in Scotland and in the UK would be useful. Clearly there are many different approaches that could be usefully employed, but the work outlined in this thesis would suggest the following methods may be appropriate and give rise to useful data that could inform further development of trauma services.

The key to researching trauma effectively lies in developing a uniform national trauma database which encompasses not only causation and acute treatment, but also includes follow up data on health status and return to work status as a core measure. This approach is labour intensive as it requires specifically trained personnel who can identify and code specific injuries but also evaluate follow up at appropriate times and with comparable and consistent measures, such as the SF36 for example. 'Labour intensive' usually translates into a specialist nurse, which is not inexpensive to a health service already overburdened with expense. However, without such a dedicated approach, data collection is haphazard and therefore ineffective for the purposes proposed.

Such an approach can not only inform morbidity outcomes as well as mortality outcome, but it can also prospectively collect data on prehospital and emergency department interventions, operative interventions, critical care activities (such as intubation) and prevention efforts in place when the injuries occurred. Thus the function of the trauma registry serves to generate data of high quality which can be used for future research efforts.

Of course, Scotland has, in the past, had the services of the Scottish Trauma Audit Group, the national trauma database which covered more than 98% of patients who were injured in Scotland. This organisation audited trauma rigorously between 1992 and 2002 and was acknowledged throughout the trauma community as having the highest of standards for scientific data collection. Despite this, STAG ceased auditing trauma in 2002 and it did not seek to collect data on morbidity, partly due to methodological difficulties (i.e. what tools were best to measure outcome) and partly due to reasons of the high workload of collecting the core dataset for each patient.

Therefore the basic infrastructure has been proven before but it clearly is an expensive approach, with a dedicated trauma data coordinator in each of 25 hospitals. Extending this approach to what is proposed would be more costly but it is the approach that is supported not only by the current work but also by the world literature on the subject.

Investment in such an approach would be large. The returns may be enough to justify their use by the potential improvement in morbidity and health status in survivors and their resultant return to tax paying status. Therefore a rigorous cost-effectiveness analysis of such an approach would also inform the literature on the subject considerably.

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32. Airway equipment in Scottish emergency departments.

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33. Is full spinal immobilisation necessary in patients with penetrating trauma?

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4: Appendices

- 1 Business card for patients, relatives and GPs
- 2 Consultants in A&E Medicine – approval letter
- 3 Consultants in A&E Medicine – consent form
- 4 Initial letter of invitation to GP
- 5 GP initial response form
- 6 GP control nomination form
- 7 GP letter of introduction to patient
- 8 Patient letter of introduction
- 9 Patient information sheet
- 10 Consent form
- 11 GP letter of introduction to control
- 12 Control letter of introduction
- 13 Control information sheet
- 14 Home visit protocol
- 15 AMA impairment score data collection form
- 16 FIM data collection form
- 17 CIQ data collection form
- 18 SF36 (UK Version 1) questionnaire
- 19 Work status questionnaire
- 20 SF36 subscale scoring algorithms: first stage
- 21 SF36 subscale scoring algorithms: second stage

Appendix 1

Business card for patients, relatives and GPs

Colin A Graham
MB ChB MPH FRCSEd FRCSGlasg FIMCRCSEd FFAEM



**Specialist Registrar
Emergency Medicine**


Accident & Emergency Department
Southern General Hospital
Govan Road
Glasgow
G51 4TF

Telephone: 0141 201 1100
Fax: 0141 201 2997
Radiopage: 07623 788346

Email: cagraham@rcsed.ac.uk


Appendix 2

Consultants in A&E Medicine – approval letter

Accident & Emergency Medicine		Southern General Hospital 1345 Govan Road Glasgow G3 7 1F	
Consultant Malcolm W G Gordon Timothy R J Park Philip I Munro			
To: Consultants in A&E Medicine Southern General Hospital; Victoria Infirmary; Western Infirmary; Glasgow Royal Infirmary.		Date May 2003 Yours Ref Our Ref CAG Enquiries to Gillian MacAlpine Extension 61712 Direct Line 0141 201 1712	
Research Study – Outcome of serious blunt injury in the West of Scotland			
<p>As you will recall, I am undertaking the above named research study, funded by the Chief Scientist Office, as part of my Clinical Research Fellowship. This study will entail interviewing survivors of blunt major trauma (without significant head injury) at least two years following trauma to identify their functional outcome.</p> <p>These data will be compared with data from a control group, to be drawn from the practice lists of the General Practitioners of the subjects, to allow comparison of trauma survivors with the Glasgow "normal".</p> <p>I write to you to ensure that you are happy for me to approach patients whose initial resuscitation and treatment were under your care in your departments. The relevant patients have been identified through the Scottish Trauma Audit Group database. With your approval, the data will be de-anonymised and used to identify patient details and their General Practitioners, to allow me to make contact.</p> <p>The supervisors for the study are Mr Malcolm Gordon, Consultant in A&E Medicine at the Southern General Hospital, along with Dr Chris Roy, Consultant in Rehabilitation Medicine at the Southern General and Professor Phil Hanton, Professor of Public Health at the University of Glasgow.</p> <p><u>I am required by the terms of approval of the Multicentre Research Ethics Committee to ask for your explicit written approval for the study to proceed as described above. I enclose a simple form for you to sign and date and return to me in the enclosed envelope.</u> Of course, if you have any objections, concerns or questions regarding the study, please get in touch with me at the Southern at your earliest convenience.</p> <p>Thank you for your time.</p> <p>With best wishes</p> <p>Yours sincerely</p> <p>Colin A Graham Specialist Registrar & NES/CSO Clinical Research Fellow in Accident & Emergency Medicine</p>			

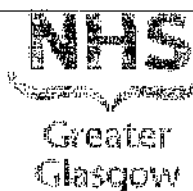
Appendix 3

Consultants in A&E Medicine – consent form

Accident & Emergency Medicine Consultants Malcolm W G Gordon MD FRCS FRCS(ED) FRCS(Orth) Timothy R J Paine MD FRCS FRCS(Orth) Philip I Murray MD FRCS(Orth) FRCS(Plast)	Southern General Hospital 1345 Govan Road Glasgow G51 4TF	
[Recipient's name & address]	Date: [date] Ward Ref: [] Out Ref: CAG	
	Enquiries to: Gillian McAlpine Extension: 4712 Direct Line: 0141 201 1712	
Consultant Consent Form		
PLEASE TICK ONE OF THE OPTIONS BELOW		
<hr/>		
YES	<input type="checkbox"/>	I consent to the researcher, Mr Colin Graham, approaching eligible patients who were under my care during their initial hospital treatment for the purposes of the research study entitled "Outcome of serious blunt injury in the West of Scotland".
<hr/>		
NO	<input type="checkbox"/>	I do not consent to my patients involvement in this research study.
<hr/>		
Signature: _____		
Print Name: _____		
Date: _____		

Appendix 4

Initial letter of invitation to GP: page 1

Accident & Emergency Medicine	Southern General Hospital 1345 Govan Road Glasgow G31 4TF	
Consultant Malcolm W G Gordon MB ChB FRCS FRCS(Orth) FRCS(Plast) Timothy R J Park MB ChB FRCS FRCS(Orth) Philip I Munro MB ChB FRCS(Orth) FRCS(Plast)		
[Recipient's name & address]	Date [date] Your Ref Our Ref CACM[Study No]	
	Enquiries to: Alice Brodie Extension: 1455 Direct Line: 0141 201 1455	
Dear [GP Name]		
Research Study: Outcome of serious blunt injury in the West of Scotland		
<p>We are conducting a case-control study into the functional outcome of survivors of major trauma who were initially treated in the hospitals within Greater Glasgow NHS Board, namely the Southern General Hospital, Victoria Infirmary, Western Infirmary and Glasgow Royal Infirmary. We are interested in patients who are at least two years post injury. The study has been funded by the Chief Scientist Office and has been approved by the Multicentre Research Ethics Committee.</p>		
<p>From our records, one of your patients (details below) appears to be eligible for this study. The study initially involves the patient completing three short questionnaires (the SF36 health status questionnaire; the Community Integration Questionnaire; a short questionnaire on work status now and at time of injury, place of residence at time of injury).</p>		
<p>Following this, I will visit the patient at home to complete the questionnaires and administer the Functional Independence Measure (a measure of functional outcome) and conduct a physical examination to allow the AMA Impairment Score to be calculated. The questionnaires will take no more than 30 minutes to complete and the visit to the patient should take no more than two hours, but in the majority of cases, it will be much shorter. Patients can elect to be seen and assessed at the Southern General Hospital as well, if they wish. In these cases, reasonable travelling expenses will be reimbursed.</p>		
<p>We do not wish to upset these patients in any way and we would be grateful if you could let us know if you know of any reason why they should not participate or if you have any objection to their participation. If you do not wish your patient to participate, please return the GP Consent Form to us and indicate the reason(s) why the patient could or should not participate.</p>		
<p>Reasons for non participation might include death in the interim period, severe post traumatic stress disorder, depression or another traumatic event in the family in the interim period. However, if you feel there is any reason not to allow your patient to participate, please let us know and there will be no further involvement in the study.</p>		
<p>If you have no objection to their participation in the study, please complete the GP Consent Form (enclosed) and return it to me in the reply paid envelope enclosed.</p>		

Appendix 4

Initial letter of invitation to GP: page 2



Once I receive this consent, I will send you a Letter of Introduction and Patient Consent Form for you to sign and forward to the patient. It is a requirement of the terms of ethical approval from the Multicentre Research Ethics Committee that all approaches to patients are from their General Practitioners. If the patient agrees to participate, they should return the consent form directly to me and I will liaise with them further.

If you are happy to allow your patient to be approached, we would request that you kindly nominate one or two suitable control patient(s) from your practice list. The only stipulation is that they should not have a history of sustaining serious injuries at any point in the past. They will undergo the same assessment process as the subjects who have sustained serious injuries.

Suitable patients may or may not be currently attending the practice with active problems, they simply need to be patients on your list. We would ask you to nominate one or two patient(s) of the same sex who are within +/- five years of the date of birth of the index patient listed below. Please complete the GP Nomination Form (enclosed) and return it to me with the GP Consent Form. We will then send you a Letter of Introduction and Information Sheet and Consent Form to sign and forward to them. As stated earlier, it is a requirement of the terms of ethical approval that all approaches to individual patients are made by the General Practitioner rather than by the researcher. If they agree to participate, they should complete the consent form and return it to me directly.

If you have any questions or concerns about the study, please contact us on the above number and we will get back to you as soon as possible.

Thank you very much for considering this request.

Yours sincerely

Colin A. Graham MB ChB, MRCP, FRCGS, FRCR, FRCR (S), FRCR (S)
Specialist Registrar & NES/CSO Clinical Research Fellow in Accident & Emergency Medicine

Patient Details

Name:

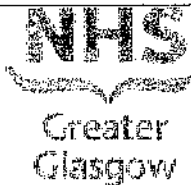
Address:

Date of Birth:

Date of Injury:

Appendix 5

GP initial response form

Accident & Emergency Medicine Consultants Malcolm W G Gordon MB ChB FRCS FRCS(Ed) Timothy R J Park MB ChB FRCS FRCS(Ed) Philip I Murray MB ChB FRCS(Ed) FRCS	Southern General Hospital 1345 Govan Road Glasgow G51 4TF
	
[Recipient's name & address]	Date [Date] Your Ref Our Ref CAG/Study No]
Enquiries to: Alice Fordin Extension: 1433 Direct Line: 0141 201 1433	

General Practitioner Consent Form

Patient Details

Name: _____

Address: _____

Date of Birth: _____

Date of Injury: _____

PLEASE TICK ONE OF THE OPTIONS BELOW

YES ☐ I am happy to allow this patient to participate in this study if they provide informed consent. There is no reason known to me why he or she should not be invited to join the study. I understand that the researcher will contact the patient directly.


NO ☐ I do not want this patient to be invited to join the study. The reason(s) are as follows:

Signature: _____

Print Name: _____

Appendix 6

GP control nomination form

Accident & Emergency Medicine Consultant Malcolm W G Gordon MD FRCS(Ed) FRCS(Glas) FRCS(Plast) Timothy LJ Park MD MRCS(Ed) FRCS(Plast) Philip I Murray MD MRCS(Ed) FRCS(Plast)	South Glasgow Hospital 1345 Govan Road Glasgow G31 1FF	
[Recipient's name & address]	Date: _____ [Date] Your Ref: _____ Our Ref: CACM[Study No] Enquiries to: Gillian MacAlpine Extension: 61712 Direct Line: 0141 201 1712	
General Practitioner Control Nomination Form		
<i>Control Patient 1</i>		
Name: _____		
Address: _____		
Date of Birth: _____		
<i>Control Patient 2</i>		
Name: _____		
Address: _____		
Date of Birth: _____		
PLEASE SIGN BELOW & RETURN THE FORM IN THE REPLY PAID ENVELOPE		
I have read and understood the Letter of Introduction to the Research Study "Outcome of serious blunt injury in the West of Scotland".		
I am happy to allow this patient to participate in this study if they provide informed consent. I know of no reason why they should not participate in this study on medical grounds.		
I understand the researcher will send me a Letter of Introduction and Consent Form for this (these) patient(s) to sign and forward to the patient to invite them to participate.		
Signature: _____		Date: _____
Print Name: _____		

Appendix 7

GP letter of introduction to patient

General Practitioner Name

Address

Address

Address

Postcode

Phone Number

Patient Name

Address

Address

Address

Postcode

[Date]

Dear [Name]

Research Study – Outcome of serious blunt injury in the West of Scotland

I have been asked by Mr Colin Graham, a Research Fellow in the Accident & Emergency Department at the Southern General Hospital, if you would be willing to take part in a study that is currently ongoing.

The study is aiming to assess how patients who have sustained major injuries are getting on a few years afterwards. It involves you filling in three short questionnaires and having an interview with Mr Graham. This interview can be done at your home or in the Hospital, and will involve a limited physical assessment along with a discussion of your questionnaires and general health. The entire process should not take more than two hours, but for most people it will be much shorter than that.

I am happy for you to take part in the study but it is up to you to decide if you want to take part or not. You are under no obligation to participate and your future medical care will not be affected in any way by your decision, whatever you decide.


I enclose a letter from Mr Graham explaining the study more fully along with a consent form and envelope. Please get in touch with him if you require more information.

Yours sincerely

[Dr GP Name]

Appendix 8

Patient letter of introduction: page 1

Accident & Emergency Medicine Consultants Malcolm W G Gordon MB ChB FRCS(Ed) FRCS(Plast) FRCS(Orth) Timothy R J Paine MB ChB FRCS(Plast) FRCS(Orth) Philip T Murray MB ChB FRCS(Plast) FRCS(Orth)	Southern General Hospital 1345 Govan Road Glasgow G51 4TF	
[Recipient's name & address]	Date [date] Your Ref Our Ref CAG	Enquiries to Gillian McAlpine Extension 61712 Direct Line 0141 201 1712
<p>Dear [Patient]</p> <p>Research Study: Outcome of serious blunt injury in the West of Scotland</p> <p>We are conducting a research study, funded by the Chief Scientist Office, into the long term outcome of survivors of serious injuries who were initially treated in the four major Glasgow hospitals. We are interested in assessing patients who sustained their injuries at least two years ago. Our aim is to determine how well people recover from their injuries, as this may influence how we treat similar patients in the future.</p> <p>Our records suggest that you may be eligible to participate this study. Your General Practitioner is happy for us to approach you to see if you would be interested in taking part.</p> <p>If you wish to take part, I will contact you to arrange an appointment to see you. I can either come to see you at your home, or you can come to the Southern General Hospital to see me. About a week before we meet, I will send you three short questionnaires about your current health and whether or not you are working at present. These questionnaires will take around 20 minutes to complete.</p> <p>When we meet, I will ask you another set of questions about how you get on in daily life and I will perform a brief physical examination to assess your ability to do the activities of normal life following your injury. The meeting might take up to two hours, but it may well be much shorter than that.</p> <p>If you want to come to the Southern General Hospital for your appointment, I will refund your travelling expenses to get you to and from the Southern to your home. Unfortunately, I cannot offer you any other payment for taking part in the study.</p>		

Appendix 8

Patient letter of introduction: page 2



When the study is complete, I would be happy to send you a summary of the results if you are interested. While there would be no benefit to individuals for participating, the results will be useful in determining how the care of future victims of trauma could be improved in Scotland.

If you are interested, please read the enclosed Information Sheet. If you have any questions, please get in touch and I will try to answer them.


If you wish to take part, you need only read and sign the Consent Form and return it to me in the reply paid envelope. We will then get in touch with you with further details about the study.


If you do not wish to participate, that is absolutely fine. You do not need to do anything else.

Thank you very much for considering our request.

Yours sincerely

Colin A Graham MB ChB MRCP FRCGS FRCR FRCR FRCR FRCR
Specialist Registrar & NES/CSO Clinical Research Fellow in Accident & Emergency Medicine

Southern General Hospital - Department of Accident & Emergency Medicine	
Research Project Outcome of serious blunt injury in the West of Scotland	
Information Sheet for Participants	
<p><i>You are being invited to take part in a research study.</i></p> <p><i>Before you decide it is important for you to understand why the research is being done and what it will involve.</i></p> <p><i>Please take time to read the following information carefully and discuss it with others if you wish.</i></p> <p><i>Ask us if there is anything that is unclear or if you would like more information.</i></p> <p><i>Take time to decide whether or not you wish to take part. Thank you.</i></p>	
<p>Why have I been selected for this study?</p> <p>Our records suggest that you sustained serious injuries a number of years ago and that you were treated at the Southern General Hospital, the Victoria Infirmary, the Western Infirmary or Glasgow Royal Infirmary. We are interested in patients like you to see how well you have recovered.</p>	
<p>What is the study aiming to do?</p> <p>We are interested in determining how well patients physically recover in the long term after sustaining serious injuries. The study is funded by the Chief Scientist Office of the Scottish Executive.</p>	
<p>What does it involve?</p> <p>If you agree to take part, you need to complete the enclosed Consent Form, return it to me in the reply paid envelope. I will then contact you to arrange a time to come and visit you at home (or you can come to the Southern General Hospital to see me if you wish). About a week before our meeting, I will send you three short questionnaires to complete, which I will pick up when we meet. <u>The three questionnaires will take no more than 20 minutes to complete.</u> When we meet, I will ask you some more questions and conduct a physical examination. Our meeting could last up to two hours, although it may be much shorter.</p>	
<p>What about my personal details?</p> <p>All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.</p>	
<p>What do I get out of it?</p> <p>I cannot offer you any payment for taking part in the study but I will reimburse reasonable travelling expenses to the Southern General Hospital, if you would rather see me there. I can send you a summary of the results of the study when it is complete, if you wish. The results will help us to understand the outcome of patients with major trauma and hopefully improve care in the future.</p>	
<p>Yes, I'm interested.</p> <p>Please complete the Consent Form and return it in the reply paid envelope as soon as possible.</p>	
<p>No, I don't want to be involved.</p> <p>That's fine - you do not need to do anything else.</p>	
<p>I want to ask some questions before I decide.</p> <p>Please don't hesitate to get in touch! Please phone 0141 201 1712, between 9am and 5pm, Monday to Friday. Give your name, telephone number and convenient time to return the call and I will get in touch.</p>	
<p>Thank you for considering this request. I look forward to hearing from you.</p>	
<p>Mr Colin A Graham Specialist Registrar and Clinical Research Fellow in Accident & Emergency Medicine MRBC Patient Information Sheet Version 1.2 17 June 2003</p>	



South Glasgow University Hospitals NHS Trust
Consent Form

PATIENT NAME..... DATE OF BIRTH.....

Outcome of serious blunt injury in the West of Scotland

To be completed by the Participant

	Please Tick	
	Yes	No
Have you read the Information Sheet for Participants?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you received satisfactory answers to all your questions?	<input type="checkbox"/>	<input type="checkbox"/>
Have you received enough information about the study?	<input type="checkbox"/>	<input type="checkbox"/>

Who have you spoken to?

Do you understand that you are free to withdraw from the study -

at any time	<input type="checkbox"/>	<input type="checkbox"/>
without having to give a reason	<input type="checkbox"/>	<input type="checkbox"/>
and without affecting your future medical care?	<input type="checkbox"/>	<input type="checkbox"/>

Do you grant permission for the researcher to access your medical records if necessary? ☐ Yes ☐ No

Do you agree to take part in this study? ☐ Yes ☐ No


Signed..... Date.....

Name in Block Letters..... Telephone Number.....

Appendix 11

GP letter of introduction to control

General Practitioner Name
Address
Address
Address
Postcode
Phone Number
Control Name
Address
Address
Address
Postcode
[Date]
Dear [Name]
Research Study – Outcome of serious blunt injury in the West of Scotland
I have been asked by Mr Colin Graham, a Research Fellow in the Accident & Emergency Department at the Southern General Hospital, if you would be willing to take part in a study that is currently ongoing.
The study is aiming to assess how patients who have sustained major injuries are getting on a few years afterwards. To do this, it is essential to also study people who have not sustained significant injuries at any stage in their lives, and it is for that reason that I have suggested that you might want to take part.
It involves you filling in three short questionnaires and having an interview with Mr Graham. This interview can be done at your home or in the Hospital, and will involve a limited physical assessment along with a discussion of your questionnaires and general health. The entire process should not take more than two hours, but for most people it will be much shorter than that.
I am happy for you to take part in the study but it is up to you to decide if you want to take part or not. You are under no obligation to participate and your future medical care will not be affected in any way by your decision. I enclose a letter from Mr Graham explaining the study more fully along with a consent form and envelope. Please get in touch with him if you require more information.
Yours sincerely
 [Dr GP Name]
MREC GP Letter of Introduction to Control Version 1.0 28 May 2003

Accident & Emergency Medicine	Southern General Hospital 1345 Govan Road Glasgow G31 1TF	
Consultant Malcolm W G Gordon MD FRCS(Ed) FRCS(Glas) Timothy R J Park MD FRCS(Ed) FRCS(Glas) Philip I Murray MD FRCS(Ed) FRCS(Glas)	Date [date] Your Ref Our Ref CAG	
[Recipient's name & address]		Enquiries to Gillian McAlpine Extension 41712 Direct Line 0141 301 1712
Dear [Control]		
Research Study: Outcome of serious blunt injury in the West of Scotland		
We are conducting a research study, funded by the Chief Scientist Office, into the long term outcome of survivors of serious injuries who were initially treated in the four major Glasgow hospitals. We are interested in assessing patients who sustained their injuries at least two years ago. Our aim is to determine how well people recover from their injuries, as this may influence how we treat similar patients in the future.		
In order to assess how well trauma victims recover, we also need to assess members of the normal population in Glasgow. They need to be the same sex and be around the same age as patients under assessment, but most importantly, they should not have suffered serious injuries at any point in the past. In particular, you should not take part in this study if you have sustained a significant head injury (for example, requiring admission to hospital, treatment in an intensive care unit or if you have had neurosurgery) at any point.		
Your General Practitioner kindly provided us with your name and address and has given us permission to approach you to ask you if you would like to participate in this research study. While we would welcome your participation in the study, you are, of course, free to refuse without giving any reason whatsoever.		
If you wish to take part, I will contact you to arrange an appointment to see you. I can either come to see you at your home, or you can come to the Southern General Hospital to see me.		
About a week before we meet, I will send you three short questionnaires about your current health and whether or not you are working at present. These questionnaires will take around 20 minutes to complete.		
When we meet, I will ask you another set of questions about how you get on in daily life and I will perform a brief physical examination to assess your ability to do the activities of normal life. The meeting might take up to two hours, but it may well be much shorter than that.		
If you want to come to the Southern General Hospital for your appointment, I will refund your travelling expenses to get you to and from the Southern to your home. Unfortunately, I cannot offer you any other payment for taking part in the study.		

Appendix 12

Control letter of introduction: page 2



When the study is complete, I would be happy to send you a summary of the results if you are interested. While there would be no benefit to individuals for participating, the results will be useful in determining how the care of future victims of trauma could be improved in Scotland.

If you are interested, please read the enclosed Information Sheet. If you have any questions, please get in touch and I will try to answer them.

If you wish to take part, you need only read and sign the Consent Form and return it to me in the reply paid envelope. We will then get in touch with you with further details about the study.


If you do not wish to participate, you do not need to do anything else.

Thank you very much for considering our request.

Yours sincerely


Colin A. Graham MB ChB MRCP FRCS FRCS(Ed) FRCS(Plast)
Specialist Registrar & NES/CSO Clinical Research Fellow in Accident & Emergency Medicine

Control information sheet

Southern General Hospital - Department of Accident & Emergency Medicine	
Research Project Outcome of serious blunt injury in the West of Scotland	
Information Sheet for Participants	
<p><i>You are being invited to take part in a research study.</i></p> <p><i>Before you decide it is important for you to understand why the research is being done and what it will involve.</i></p> <p><i>Please take time to read the following information carefully and discuss it with others if you wish.</i></p> <p><i>Ask us if there is anything that is not clear or if you would like more information.</i></p> <p><i>Take time to decide whether or not you wish to take part. Thank you.</i></p>	
<p>Why have I been selected for this study?</p> <p>Your General Practitioner gave us permission to contact you to see if you would like to participate in this research project. We are trying to find out how well patients recover after suffering serious injuries and to do this, we need to compare them to a group of people who have never sustained serious injuries. That is why we have contacted you.</p>	
<p>What is the study aiming to do?</p> <p>We are interested in determining how well patients physically recover in the long term after sustaining serious injuries. The study is funded by the Chief Scientist Office of the Scottish Executive.</p>	
<p>What does it involve?</p> <p>If you agree to take part, you need to complete the enclosed Consent Form return it to me in the reply paid envelope. I will then contact you to arrange a time to come and visit you at home (or you can come to the Southern General Hospital to see me if you wish). About a week before our meeting, I will send you three short questionnaires to complete, which I will pick up when we meet. <u>The three questionnaires will take no more than 20 minutes to complete.</u> When we meet, I will ask you some more questions and conduct a physical examination. Our meeting could last up to two hours, although it may be much shorter.</p>	
<p>What about my personal details?</p> <p>All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.</p>	
<p>What do I get out of it?</p> <p>I cannot offer you any payment for taking part in the study but I will reimburse reasonable travelling expenses to the Southern General Hospital, if you would rather see me there. I can send you a summary of the results of the study when it is complete, if you wish. The results will help us to understand the outcome of patients with major trauma and hopefully improve care in the future.</p>	
<p>Yes, I'm interested.</p> <p>Please complete the Consent Form and return it in the reply paid envelope as soon as possible.</p>	
<p>No, I don't want to be involved.</p> <p>That's fine - you do not need to do anything else.</p>	
<p>I want to ask some questions before I decide.</p> <p>Please don't hesitate to get in touch! Please phone 0141 201 1712, between 9am and 5pm, Monday to Friday. Give your name, telephone number and convenient time to return the call and I will get in touch.</p>	
<p>Thank you for considering this request. I look forward to hearing from you.</p>	
<p>Mr Colin A. Graham Specialist Registrar and Clinical Research Fellow in Accident & Emergency Medicine MEIC Control Information Sheet Version 1.1 17 June 2003</p>	

Appendix 14

Home visit protocol

Accident & Emergency Medicine Consultant Malcolm W G Gordon Time for R J Park Philip I Munn	Southern General Hospital 1345 Govan Road Glasgow GSL 4TF	
Date Your Ref Our Ref CAG		
Enquiries to Gillian McAldine Extension 41712 Direct Line 0141 201 1712		
Protocol for Home Visits		
<ul style="list-style-type: none">• The time and date of attendance will be pre-arranged with the subject by telephone.• The subject will be given the option at that time of attending the Hospital for the interview and physical assessment or the alternative of the researcher visiting the patient at home.• The subject will be told that they may have a relative or close friend present during the interview and assessment if they wish.• The researcher will attend the patient (or vice versa for hospital visits) at the appointed hour and introduce himself and offer his standard NHS Identification Card for scrutiny.• After a brief verbal introduction, the researcher will go over the completed questionnaires and ensure that they have been fully completed; in cases where there are missing data, attempts will be made to fill in any gaps by verbal discussion with the subject. This will usually take no more than 15 minutes but rarely may take up to 45 minutes in cases where there have been difficulties in completing the questionnaires.• Following the completion of the questionnaires, the Functional Independence Measure will be estimated by asking questions about activities of daily living and assessing functional ability. This will take around 15 minutes.• Finally, the American Medical Association Impairment Score will be calculated by briefly examining any visible scars, assessing movements of the limbs, and assessing walking ability (gait). This will usually take less than 30 minutes but again may take up to 60 minutes in patients with severe physical impairment.• The interview will be concluded with an opportunity for the subject to ask any questions of the researcher and a card with contact details will be left with the subject to allow the subject to make contact if distress or further questions arise.		
Colin A Graham Specialist Registrar & NESACSO Clinical Research Fellow in Accident & Emergency Medicine		

Appendix 15

AMA impairment score data collection form: page 1

Sample Report for Permanent Medical Impairment	
Identifiers:	
Patient Name:	
Address:	
City:	
Date of birth:	
Date of injury or illness:	
Examination data:	
Date of exam by examining physician:	
Examination location:	
Examining physician:	
Introduction: Purpose: Impairment in life (education, personal enjoy, work or compensation) and prognosis (also determined by exam, patient request, location of examination)	
History: Chief complaint, history of injury or illness, occupational history, past medical history, family history, social history, Review of systems	
Medical record review: Chronology of medical evaluation, diagnostic studies, and treatment for the injury or illness	
Physical examination:	

Appendix 15

AMA impairment score data collection form: page 2

Diagnostic studies: 			
On/needs and impairments: (If requested, identify and a baseline, causation, exacerbation, restriction, accommodation, sensitive demands) 			
Impairment Rating between RMR and/or function, limitations of activities of daily living, prognosis 			
3			
Impairment Rating and Rationale: Organ system and whole person impairment			
Body part or system	Chapter No.	Subchapter No.	% Impairment of the Whole Person
a			
b			
c			
d			
Calculated and whole person impairment: _____ % (Discussion of rationale of impairment rating and any possible inconsistencies in the documentation)			
Recommendations: Further diagnostic or therapeutic follow-up care 			
Work ability, work restrictions (if requested), review abilities and limitations in reference to essential job activities 			

Appendix 16

FIM data collection form

	ADMISSION	DISCHARGE	FOLLOW-UP
Self-Care			
A. Eating			
B. Grooming			
C. Bathing			
D. Dressing – Upper Body			
E. Dressing – Lower Body			
F. Toileting			
Sphincter Control			
G. Bladder Management			
H. Bowel Management			
Transfers			
I. Bed, Chair, Wheelchair			
J. Toilet			
K. Tub, Shower			
Locomotion			
L. Walk/Wheelchair			
M. Stairs			
<i>Motor Subtotal Score</i>			
Communication			
N. Comprehension			
O. Expression			
Social Cognition			
P. Social Interaction			
Q. Problem Solving			
R. Memory			
<i>Cognitive Subtotal Score</i>			
TOTAL FIM Score			

L E V E L S	Independent 7 Complete Independence (Timely, Safely) 6 Modified Independence (Device)	NO HELPER
	Modified Dependence 5 Supervision (Subject = 100%+) 4 Minimal Assist (Subject = 75%+) 3 Moderate Assist (Subject = 50%+)	HELPER
Complete Dependence 2 Maximal Assist (Subject = 25%+) 1 Total Assist (Subject = less than 25%)		
Note: Leave no blanks. Enter 1 if patient is not testable due to risk.		

COMMUNITY INTEGRATION QUESTIONNAIRE	
Subject: _____	Date: _____
1. Who usually does the shopping for groceries or other necessities in your household?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else
2. Who usually prepares meals in your household?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else
3. In your home who usually does the everyday housework?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else
4. Who usually cares for the children in your home?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else <input type="radio"/> Not applicable, No children under 17 in the home
5. Who usually plans social arrangements such as got-togethers with family and friends?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else
6. Who usually looks after your personal finances, such as banking or paying bills?	<input type="radio"/> Yourself alone <input type="radio"/> Yourself and someone else <input type="radio"/> Someone else
7. Approximately how many times a month do you usually participate in shopping outside your home?	<input type="radio"/> Never <input type="radio"/> 1 - 4 times <input type="radio"/> 5 or more
8. Approximately how many times a month do you usually participate in leisure activities such as movies, sports, restaurants, etc.	<input type="radio"/> Never <input type="radio"/> 1 - 4 times <input type="radio"/> 5 or more
9. Approximately how many times a month do you usually visit your friends or relatives?	<input type="radio"/> Never <input type="radio"/> 1 - 4 times <input type="radio"/> 5 or more
10. When you participate in leisure activities do you usually do this alone or with others?	<input type="radio"/> Mostly alone <input type="radio"/> Mostly with friends who have head injuries <input type="radio"/> Mostly with family members <input type="radio"/> Mostly with friends who do not have head injuries <input type="radio"/> With a combination of family and friends

Please complete page two

COMMUNITY INTEGRATION QUESTIONNAIRE		(Page 2)
11. Do you have a best friend with whom you confide?	<input type="radio"/> Yes <input type="radio"/> No	
12. How often do you travel outside the home?	<input type="radio"/> Almost every day <input type="radio"/> Almost every week <input type="radio"/> Seldom/never (less than once per week)	
13. Please choose the answer that best corresponds to your current (during the past month) work situation:	<input type="radio"/> Full-time (more than 20 hours/week) <input type="radio"/> Part-time (less than or equal to 20 hrs/week) <input type="radio"/> Not working, but actively looking for work <input type="radio"/> Not working, not looking for work <input type="radio"/> Not applicable, retired due to age	
14. Please choose the answer that best corresponds to your current (during the past month) school or training program situation:	<input type="radio"/> Full-time <input type="radio"/> Part-time <input type="radio"/> Not attending school, or training program <input type="radio"/> Not applicable, retired due to age	
15. In the past month, how often did you engage in volunteer activities?	<input type="radio"/> Never <input type="radio"/> 1 - 4 times <input type="radio"/> 5 or more	
Comments:		

SF36 (UK Version 1) questionnaire: page 1

SF-36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

- Excellent.....1
 Very good.....2
 Good.....3
 Fair.....4
 Poor.....5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

- Much better now than one year ago.....1
 Somewhat better now than one year ago.....2
 About the same as one year ago.....3
 Somewhat worse now than one year ago.....4
 Much worse now than one year ago.....5

1
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 (SF-36 Standard U.K. Version 1.0)

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing <u>one</u> flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking <u>more than a mile</u>	1	2	3
h. Walking <u>half a mile</u>	1	2	3
i. Walking <u>one hundred yards</u>	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down on the <u>amount of time</u> you spent on work or other activities	1	2
b. <u>Accomplished less</u> than you would like	1	2
c. Were limited in the <u>kind</u> of work or other activities	1	2
d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	1	2

2

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 (SF-36 Standard U.K. Version 1.0)

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down on the <u>amount of time</u> you spent on work or other activities	1	2
b. <u>Accomplished less</u> than you would like	1	2
c. Didn't do work or other activities as <u>carefully</u> as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(circle one)

Not at all1
 Slightly2
 Moderately3
 Quite a bit4
 Extremely5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

None1
 Very mild2
 Mild3
 Moderate4
 Severe5
 Very severe6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all1
 A little bit.....2
 Moderately.....3
 Quite a bit.....4
 Extremely.....5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and low?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

- All of the time.....1
 Most of the time.....2
 Some of the time.....3
 A little of the time.....4
 None of the time.....5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Appendix 19

Work status questionnaire

Supplementary Questionnaire

Please complete the following questions as best you can. The researcher will get the questionnaires back when you meet with him soon. If you are not sure how to answer any of the questions, don't worry, the researcher will answer any questions and help you to complete the forms when you meet.

1 Please give your current postcode

--	--	--	--	--	--	--	--

2 Please give the postcode for the address you were living at when you sustained your injuries

--	--	--	--	--	--	--	--

If you cannot remember the postcode, please give details of the address instead

3 What is your current job?

For Question 4, please tick the one box that applies to you

4 Are you working now?

- ☐ Yes, I am doing the same job as I did before I was injured
- ☐ Yes, I am doing a similar job but doing different duties as a result of my injuries
- ☐ Yes, but I had to change job or change employer as a result of my injuries
- ☐ No, I am not currently working (Go to Question 5)

Only answer Question 5 if you ticked the last box on Question 4 (you are not currently working)

5 If you are not currently working

- ☐ I could go back to a similar job as I had before my injuries
- ☐ I could go back to a lighter job now as a result of my injuries
- ☐ I will never work again as a result of my injuries
- ☐ I am receiving state benefits

Please tell us what type(s) of benefits you are currently receiving

Thank you for completing this questionnaire

Appendix 20

SF36 subscale scoring algorithms: first stage

Physical function (PF)

Q3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j Yes, limited a lot = 1
Yes, limited a little = 2
No, not limited at all = 3

Role limitation due to physical problems (RP)

Q4a, 4b, 4c, 4d Yes = 1
No = 2

Bodily pain (BP)

Q7 None = 6.0
Very mild = 5.4
Mild = 4.2
Moderate = 3.1
Severe = 2.2
Very severe = 1.0

If both Q7 and Q8 answered:

Q8 Not at all = 6 if Q7 = "None"
response Not at all = 5 if Q7 = any other

A little bit = 4
Moderate = 3
Quite a bit = 2
Extremely = 1

If Q7 not answered:

Q8 Not at all = 6.0
A little bit = 4.75
Moderate = 3.5
Quite a bit = 2.25
Extremely = 1.0

General health perception (GH)

Q1	Excellent = 5.0 Very good = 4.4 Good = 3.4 Fair = 2.0 Poor = 1.0
Q11a, 11c	Definitely true = 1 Mostly true = 2 Not sure = 3 Mostly false = 4 Definitely false = 5
Q11b, 11d	Definitely true = 5 Mostly true = 4 Not sure = 3 Mostly false = 2 Definitely false = 1

Vitality (VT)

Q9a, 9e	All of the time = 6 Most of the time = 5 A good bit of the time = 4 Some of the time = 3 A little of the time = 2 None of the time = 1
Q9g, 9i	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6

Social functioning (SF)

Q6	Not at all = 5 Slightly = 4 Moderately = 3 Quite a bit = 2 Extremely = 1
Q10	All of the time = 1 Most of the time = 2 Some of the time = 3 A little of the time = 4 None of the time = 5

Role limitation due to emotional problems (RE)

Q5a, 5b, 5c

Yes = 1

No = 2

Mental health (MH)

Q9b, 9c, 9f

All of the time = 1

Most of the time = 2

A good bit of the time = 3

Some of the time = 4

A little of the time = 5

None of the time = 6

Q9d, 9h

All of the time = 6

Most of the time = 5

A good bit of the time = 4

Some of the time = 3

A little of the time = 2

None of the time = 1

Appendix 21

SF36 subscale scoring algorithms: second stage

Physical function (PF)

$$PF = 3a+3b+3c+3d+3e+3f+3g+3h+3i+3j$$

$$PF \text{ score} = ((PF-10)/20)*100$$

Role limitation due to physical problems (RP)

$$RP = 4a+4b+4c+4d$$

$$RP \text{ score} = (RP-4/4)*100$$

Bodily pain (BP)

$$BP = 7+8$$

$$BP \text{ score} = ((BP-2)/10)*100$$

General health (GH)

$$GH = 1+11a+11b+11c+11d$$

$$GH \text{ score} = ((GH-5)/20)*100$$

Vitality (VT)

$$VT = 9a+9e+9g+9i$$

$$VT \text{ score} = ((VT-4)/20)*100$$

Social functioning (SF)

$$SF = 6+10$$

$$SF \text{ score} = ((SF-2)/8)*100$$

Role limitation due to emotional problems (RE)

$$RE = 5a+5b+5c$$

$$RE \text{ score} = (RE-3/3)*100$$

Mental health (MH)

$$MH = 9b+9c+9d+9f+9h$$

$$MH \text{ score} = ((MH-5)/25)*100$$

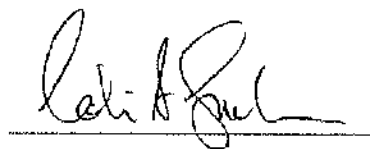
5: Declaration

I, Colin Alexander Graham, declare that I was the sole and principal investigator for the study described in Section A of this thesis.

For the studies described in Section B, I was principal investigator and writer for the studies described in Sections B1, B2, B3, B4 and B5 and completed 75-90% of each individual study.

For the study described in Section B6, I was responsible for around 30% of the study design, analysis and writing up of the paper. Sections C and D of this thesis are entirely my own work.

The writing of this thesis was done solely by me, and represents my own work except for the parts described above. The subject matter described in this thesis has not been submitted previously for any other degree or award.

A handwritten signature in black ink, appearing to read 'Colin A. Graham', is written over a horizontal line.

Colin A Graham

Hong Kong

23 August 2007

